98-1307

No. [redacted]

In The
Supreme Court of the United States
October Term, 1998

DONNA E. SHALALA,
SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,
PETITIONERS,

v.

ILLINOIS COUNCIL ON LONG TERM CARE, INC.

On Petition For A Writ of Certiorari
To The United States Court of Appeals
For the Seventh Circuit

CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the court of appeals erred in dismissing cross-petitioner's challenge to the vagueness of the regulations at 42 C.F.R. § 488.300 *et seq.* as unripe, where the challenged regulations have been enforced for over three years and where exhaustion of administrative remedies would be futile?

PARTIES TO THE PROCEEDING

For Cross-Petitioner's statement of "Parties to the Proceeding", see Brief in Opposition at II. As stated therein and in accordance with Supreme Court Rule 29.1, the Illinois Council on Long Term Care, Inc., states that it has no affiliated corporations, either as parent, subsidiary or otherwise.

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No. 98-1109

In The
SUPREME COURT OF THE UNITED STATES
October Term, 1998

DONNA E. SHALALA,
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CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI

CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI

The Illinois Council on Long Term Care, Inc. (the "Council"), respectfully submits this conditional cross-petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Seventh Circuit in this case.

OPINIONS BELOW

The opinions below are reproduced in the Petitioner Shalala's Appendix ("Pet. App."). The opinion of the court of appeals is reported at 143 F.3d 1072. Pet. App. 1a-12a. The opinion of the district court opinion is unreported. Pet. App. 13a-21a.

JURISDICTION

The judgment of the court of appeals was entered on May 8, 1998. Petitioner Shalala filed a timely petition for a writ of certiorari on January 12, 1999. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

For relevant statutory provisions, *see* Petitioner Shalala's Petition For a Writ of Certiorari at 2 and Respondent Council's Brief in Opposition at 1 ("Opp. Br.").

STATEMENT OF THE CASE

Respondent and cross-petitioner Illinois Council on Long Term Care, Inc., relies upon and incorporates by reference the Statement of the Case in Respondent's Brief in Opposition. The following additional facts are relevant to the issue raised in this conditional cross-petition.

When the Council filed its complaint below, the Secretary filed a motion to dismiss, or in the alternative, for summary judgment, contending that the district court lacked subject matter jurisdiction and that the Council failed to state a claim for which relief can be granted. In response, the Council filed a cross-motion for preliminary injunction. At the hearing on the motions, the district court considered only the Secretary's motion to dismiss for lack of jurisdiction. The district court then granted the motion to dismiss, denied the Secretary's alternative motion for summary judgment as moot, and also denied the Council's motion for preliminary injunction as moot. Pet. App. at 21a. The Council appealed that order. Accordingly, the procedural posture of the case before the Seventh Circuit was an appeal of an order granting a motion to dismiss for lack of subject matter jurisdiction.

The Seventh Circuit reversed the district court's dismissal for lack of subject matter jurisdiction regarding all counts of the complaint, both those arising under Medicare (Pet. App. 3a-7a), and those arising under Medicaid (Pet. App. 7a-9a). Nevertheless, the Seventh Circuit affirmed the dismissal of the counts in the amended complaint[1] that allege that the new regulations are unconstitutionally vague on *ripeness* grounds. Pet. App. 10a-12a. The Council seeks review of the Seventh Circuit's conclusion that the vagueness challenge is unripe.

Because this appeal arises from an order granting a motion to dismiss, the allegations of the Council's complaint are taken as true. The Council alleges that the regulations are unconstitutionally vague because of the Secretary's failure to define certain "scope and severity factors" inspectors use to determine whether a facility is in substantial compliance with the regulations. Am. Compl. ¶ 86. Those factors are set forth at 42 C.F.R. § 488.404. The factors also appear on an enforcement "grid" that is used by inspectors and is included in the State Operations Manual. Am. Compl. Ex. A. The grid was published in 59 Fed. Reg. 56183 (November 10, 1994). *See* Grid, Appendix hereto at A-1 ("App.").

To determine whether the Council's vagueness challenge is ripe, it is necessary for this Court to understand how inspectors use the grid and the scope and severity factors. The "severity" factors are listed vertically on the left side of the grid and range from "No Actual Harm with Potential for Minimal Harm" to "Immediate Jeopardy to Resident Health or Safety." The "scope" factors, listed horizontally across the bottom of the grid, are "Isolated," "Pattern" and "Widespread." When an inspector encoun-

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[1] Amended Complaint, Counts I (Medicaid) and IV (Medicare).

ters a deficiency, he or she must determine which scope and severity factors to apply and then plot the deficiency in one of the boxes in the grid. "Substantial Compliance" exists only when the deficiency falls in boxes A, B, or C of the grid. On the other hand, "Substandard Quality of Care" may exist when a deficiency falls in boxes F, H, I, J, K, or L. Different remedies are imposed depending on the box wherein the deficiency is plotted. (*See* the Remedy Categories listed below the grid, and compare to actions that are "Required" and "Optional" within each box.) For example, if a deficiency is plotted in box F, denial of payment and/or civil money penalties of up to $3,000 per day is required.

The only scope and severity factor that is defined in the regulations is "immediate jeopardy." 42 C.F.R. § 488.301. All the other factors are left undefined in the regulations. This lack of specificity has resulted in arbitrary and discriminatory enforcement of the regulations. Am. Compl. ¶ 87. Inspectors have complete discretion to determine the scope and severity factors for a deficiency. Inspectors can plot a deficiency in virtually any box in the grid and thereby instigate remedies on an *ad hoc*, subjective basis. Certain Illinois nursing facilities have been found out of compliance and providing "substandard quality of care," while others with the same types of deficiencies have been found in "substantial compliance." Am. Compl. ¶ 87. This lack of definition, and the unfettered discretion of inspectors, deprives the Council's members of both fair enforcement of the regulations and fair notice of the deficiencies for which they may be penalized, in violation of their rights to due process under the Fifth and Fourteenth Amendments. Am. Compl. ¶ 88.

Under the regulations, a facility wishing to appeal an enforcement remedy cannot challenge the choice of the

remedy or the scope and severity designations. 42 C.F.R. § 488.408(g)(2) ("A facility may not appeal the choice of remedy, including the factors considered by HCFA or the State in selecting the remedy, specified in § 488.404."). Because the scope and severity of a remedy cannot be challenged in an administrative hearing, published decisions of administrative law judges or administrative appeal boards do not discuss scope and severity factors or whether a particular remedy is appropriate. Thus, no body of administrative law is evolving that clarifies the meaning or application of the scope and severity factors.

REASONS FOR GRANTING CONDITIONAL CROSS-PETITION FOR WRIT OF CERTIORARI

I. The Conditional Cross-petition Should Be Granted To Review The Ripeness Of The Council's Vagueness Challenge Because It Is An Important Issue That Is Intertwined With The Jurisdictional Issue Raised By The Secretary.

A. The Council's Vagueness Challenge Raises Issues Of Far-reaching Importance.

If this Court grants the Secretary's petition for writ of certiorari on the jurisdictional issue, it should also consider the ripeness of the Council's vagueness challenge. Thousands of nursing homes nationwide that participate in Medicare and Medicaid are regularly surveyed based on the enforcement grid. App. at 1a. If, as the Council contends, the grid and corresponding regulations are unconstitutionally vague, an entire industry is being unjustly impacted. Nursing homes are being deprived of fair enforcement of the regulations and fair notice of the deficiencies for which they will be penalized, in violation of their due process rights under the Fifth and Fourteenth Amendments. Am.

Compl. ¶ 88. Moreover, both the Secretary and nursing home residents have a substantial interest in ensuring that good nursing homes participating in Medicare and Medicaid are not terminated arbitrarily. Yet because of the vagueness of the regulations and the broad discretion given to inspectors, the government could potentially terminate provider agreements for the majority of nursing facilities participating in Medicare and Medicaid nationwide.

Ripeness is an important issue in actions like this one seeking declaratory and injunctive relief, and the lower courts need this Court's guidance regarding its application. "The injunctive and declaratory judgment remedies are discretionary, and courts traditionally have been reluctant to apply them to administrative determinations unless these are in the context of a controversy 'ripe' for judicial resolution." *Abbott Laboratories v. Gardner*, 387 U.S. 136, 148 (1967). If federal question jurisdiction exists for constitutional and statutory challenges to regulations, lower courts should not too hastily dismiss such challenges on ripeness grounds. Substantial constitutional violations could go uncorrected. On the other hand, limited judicial resources demand that courts not entertain jurisdiction in cases that are truly unripe. If this Court entertains the jurisdictional issue the Secretary proposes, the lower courts also need this Court's analysis of the ripeness the Council's claims.

B. The Jurisdictional And Ripeness Issues In This Case Are Interrelated.

The major considerations for determining whether jurisdiction exists for the Council's constitutional and statutory claims also bear on whether the Council's vagueness claim is ripe. This Court has stated that the ripeness doctrine and the application of jurisdiction precluding statutes like § 405(h) "dovetail neatly." *See Reno v. Catholic*

Social Services, Inc., 509 U.S. 43, 60 (1993). The jurisdictional and ripeness issues also "dovetail" here.

As demonstrated in the Council's Brief in Opposition, the Council's statutory and constitutional claims cannot be considered in the administrative review process. Opp. Br. at 3. That is a major reason why § 1331 jurisdiction exists. As this Court reiterated in *Thunder Basin Coal Company v. Reich*, 510 U.S. 200, 207 (1994), whether "a statute is intended to preclude initial judicial review is determined from the statute's language, structure, and purpose, its legislative history, and *whether the claims can be afforded meaningful review.*" (emphasis added) (citations omitted). *See also McNary v. Haitian Refugee Center*, 498 U.S. 479, 484, 496-97 (1991) (concluding that the limited post-exhaustion judicial review provided by the INA could not adequately address the statutory and constitutional claims at issue).

This same consideration weighs heavily in analyzing ripeness. This Court recognized in *Reno v. Catholic Social Services, Inc.*, 509 U.S. 43 (1993), the link between the adequacy of administrative review and ripeness. *Reno* considered whether federal question jurisdiction existed for two class actions challenging INS regulations. This Court concluded that jurisdiction existed and was not barred by § 1255a(f) of the Immigration Reform and Control Act. *Reno*, 509 U.S. 56-57. However, this Court also concluded that certain class members' claims were not ripe because an adequate administrative review mechanism existed. The *Reno* Court observed that "plaintiffs do not argue that this limited scheme would afford them inadequate review of a determination based on the regulations they challenge. . . ." *Id.* at 60-61. This Court also stated that "plaintiffs' situation is thus different from that of the '17 unsuccessful individual SAW applicants' in *McNary* whose procedural objections, we

concluded, could receive no practical judicial review within the scheme established by 8 U.S.C. § 1160(e)." *Reno*, 509 U.S. at 61 (citation omitted).

By contrast, the *Reno* Court found that claims by any class member subjected to a "front-desking" procedure would be ripe because he "would have no formal denial to appeal to the Associate Commissioner for Examinations nor would he have an opportunity to build an administrative record on which judicial review might be based." *Id.* 509 U.S. at 63-64 (following *McNary*). Hence, this Court has recognized that both jurisdiction and ripeness are determined to some extent by the adequacy of the administrative review mechanism to adjudicate the claims at issue. That is the situation here. Because the Secretary's administrative review system is inadequate to deal with the statutory and constitutional claims at issue, federal question jurisdiction exists, and the Council's vagueness challenge is ripe. In this case, the issues of jurisdiction and ripeness are closely related, and just resolution of this case requires this Court to consider both issues, just as it did in *Abbott Laboratories v. Gardner*, 387 U.S. 136, 149 (1967); *Toilet Goods Assn., Inc. v. Gardner*, 387 U.S. 158, 164 (1967); and *Reno v. Catholic Social Services, Inc.*, 509 U.S. 43 (1993).

II. Under This Court's Controlling Precedent, The Council's Vagueness Challenge Is Ripe For Adjudication.

The Seventh Circuit erred in concluding that the vagueness challenge was unripe. The basic rationale of the ripeness doctrine "is to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the

challenging parties." *Abbott Laboratories v. Gardner*, 387 U.S. 136 148-49 (1967). This Court's long-standing test for ripeness is two-fold, "requiring us to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Id.* at 149. This Court has relied on the *Abbott Laboratories* test repeatedly.[2] Under both *Abbott Laboratories* factors, the Council's vagueness challenge is ripe.

The issues are fit for judicial resolution for several reasons. First, these regulations have been in force since 1995 and under them nursing homes have been, and continue to be, surveyed regularly. Approximately 70% have been found deficient. Pet. App. 2a. This is not like the situation in *Ohio Forestry Association, Inc. v. Sierra Club*, 523 U.S. 726 (1998), where logging under the challenged land use plan could not occur until numerous procedural requirements were fulfilled, and where this Court concluded that the challenger could wait until the threatened harm was more imminent.

Second, the courts will not benefit by further administrative review. A district court reviewing a final decision by the secretary is limited to the administrative record. 42 U.S.C. § 405(g) ("The Court shall have power to enter, *upon the pleadings and transcript of the record*, a judgment affirming, modifying, or reversing

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[2] *E.g., Ohio Forestry Association, Inc. v. Sierra Club*, 523 U.S. 726, 118 S.Ct. 1665, 1670 (1998); *Reno v. Catholic Social Services, Inc.*, 509 U.S. 43, 71 (1993) (O'Connor concurring) (citing *Thomas v. Union Carbide Agricultural Products Co.*, 473 U.S. 568, 581-82 (1985); *Pacific Gas & Elec. Co. v. State Energy Resources Conservation and Development Comm'n*, 461 U.S. 109 (1983); *EPA v. National Crushed Stone Assn.*, 449 U.S. 64, 72-73 (1980)).

the decision" (emphasis added)). The vagueness of the regulations cannot be challenged in the administrative review process. Administrative law judges have no power to entertain such claims. Opp. Br. at 3. Accordingly, there would not be an adequate "administrative record" regarding the vagueness of the regulations for a federal court to review on appeal. Moreover, a district court exercising § 1331 jurisdiction that is considering the vagueness of the regulations would benefit from having evidence of how the regulations have been applied in multiple situations. A trade association like the Council can offer substantial evidence regarding how the regulations have been applied against its members in different situations to prove vagueness. This Court recognized in *McNary* that a federal district court sitting as a trial court would be in a superior position to entertain such a challenge compared to a court limited to an administrative record: "Not only would a court of appeals reviewing an individual SAW determination therefore most likely not have an adequate record as to the pattern of INS' allegedly unconstitutional practices, but it also would lack the fact finding and record-developing capabilities of a federal district court." *McNary*, 498 U.S. at 497. A federal district court exercising § 1331 jurisdiction, with its fact-finding and record-developing capabilities, is a better forum to consider a constitutional vagueness challenge than a federal court considering an individual administrative appeal under § 405(g).

Third, the Council's vagueness challenge attacks a widespread systemic problem — the Secretary's failure to adequately define the scope and severity factors. The vagueness of the regulations is readily apparent from the general failure to provide concrete definitions. The issue need not be distilled through some prolonged and futile administrative appeal. "[T]his is not a situation in which

consideration of the underlying legal issues would necessarily be facilitated if they were raised in the context of a specific attempt to enforce the regulations." *Gardner v. Toilet Goods Assn., Inc.*, 387 U.S. 167, 171 (1967). The issue is fit for judicial resolution.

Moreover, withholding court consideration would be burdensome to the Council's members, the second factor in the *Abbott Laboratories* analysis. Under the administrative review mechanism, the only way to preserve appeal rights is to refuse to correct an alleged deficiency and risk termination of one's provider agreement. Opp. Br. at 2. Even if a nursing home did refuse to correct a deficiency and appealed the matter through the administrative process, it would have virtually no opportunity to create an administrative record to support its vagueness challenge that a federal court could review on appeal thereafter.

For all these reasons the Council's vagueness challenge meets the *Abbott Laboratories* test for ripeness. The Seventh Circuit failed to apply the *Abbott Laboratories* test and its decision on ripeness should therefore be reversed.

III. The Seventh Circuit's Ripeness Analysis Is Flawed Because There Will Be No Administrative Law Decisions To Clarify The Regulations With The Passage Of Time.

Rather than applying the *Abbott Laboratories* factors to determine ripeness, the Seventh Circuit relied on the concept that "[a]gencies may use ambiguous standards that acquire meaning through the process of application, just as the common law does." Pet. App. 10a. (citing cases). The court also said that the Council "cannot ask for an all-at-once review but must wait until the agency has worked through the process of adding detail in administrative adjudication." Pet. App. 11a. Such reasoning *assumes* that

standards will get clearer over time through administrative decisions. That assumption does not apply here.

Under the regulations, a facility wishing to appeal an enforcement remedy cannot challenge the choice of the remedy or the scope and severity designations. 42 C.F.R. § 488.408(g)(2) ("A facility may not appeal the choice of remedy, including the factors considered by HCFA or the State in selecting the remedy, specified in § 488.404."). Because the scope and severity of a remedy cannot be challenged in an administrative hearing, published decisions of administrative law judges do not discuss scope and severity factors or the appropriateness of a particular remedy. Thus, no body of administrative law is evolving that clarifies the meaning or application of the scope and severity factors. By failing to define the scope and severity factors, and by giving inspectors *unreviewable* discretion to select remedies, the Secretary has ensured that the standards will remain subjective and unclear. In these circumstances, exhaustion of administrative remedies is futile, and therefore, the issue is ripe.

The Seventh Circuit also said the Council cannot mount a vagueness challenge without "facts of the case at hand." Pet. App. 10a (citing cases). The court seems to imply that the Council's complaint fails because it did not set forth specific fact scenarios wherein remedies were imposed. However, this confuses the "notice pleading" requirements with the burden of proof at trial. The Council's complaint satisfied the notice pleading standards of FRCP 8(a). The complaint need not have alleged individual fact patterns to state a claim that the regulations were vague. At trial, the Council can provide multiple examples of how the regulations have been randomly applied against its members. Federal courts are not to invent "heightened pleading standards" beyond the usual pleading requirements of FRCP

8(a). *Leatherman v. Tarrant County Narcotics Intelligence & Coordination Unit*, 507 U.S. 163 (1993) (courts may not apply a heightened pleading standard in civil rights cases alleging municipal liability under 42 U.S.C. § 1983). The Seventh Circuit should at least have remanded the vagueness counts for further factual development to determine ripeness, as it did with the due process claim. Pet. App. at 12a. Outright dismissal without giving leave to amend was clearly erroneous, especially after having concluded that jurisdiction existed for the claim. It was also contrary to this Court's approach in *Reno v. Catholic Social Services, Inc.*, 509 U.S. 43, 66-67 (1993) (remanding for district courts to determine which class members were front-desked for purposes of determining ripeness).

CONCLUSION

For the foregoing reasons, the conditional cross-petition should be granted and the dismissal of the Council's challenge to the vagueness of the regulations should be reversed.

Respectfully Submitted,

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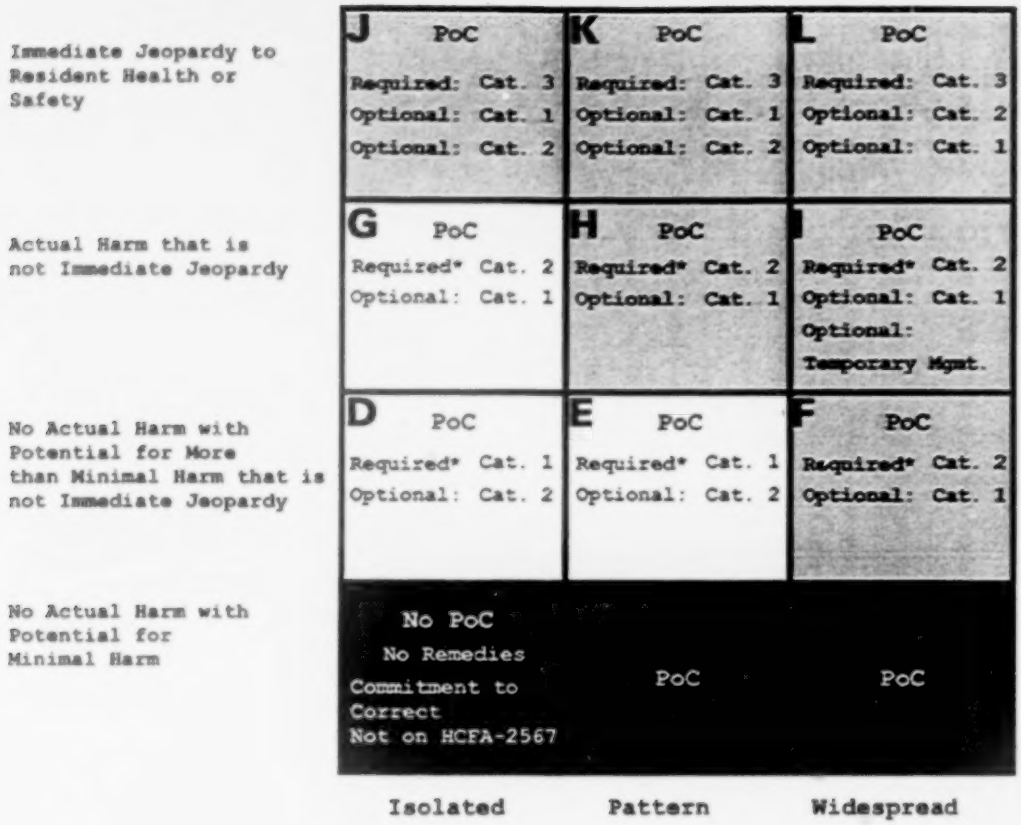

Substandard quality of care: any deficiency in §483.13 Resident Behavior and Facility Practices, §483.15 Quality of Life, or in §483.25, Quality of Care that constitutes: immediate jeopardy to resident health or safety; or, a pattern of or widespread actual harm that is not immediate jeopardy; or, a widespread potential for more than minimal harm that is not immediate jeopardy, with no actual harm.

Substantial compliance

REMEDY CATEGORIES

Category 1 (Cat. 1)

Directed Plan of Correction
State Monitor; and/or
Directed In-Service Training

Category 2 (Cat. 2)

Denial of Payment for New Admissions;
Denial of Payment for All Individuals; imposed by HCFA; and/or
Civil Money Penalties $50 - $3,000/day

Category 3 (Cat. 3)

Temporary Management Termination

Optional:

Civil Money Penalties $3,050 - $10,000/day

Denial of Payment for New Admissions must be imposed when a facility is not in substantial compliance within 3 months after being found out of compliance.

Denial of Payment and State Monitoring must be imposed when a facility has been found to have provided substandard quality of care on three consecutive standard surveys.

Note: Termination may be imposed by the State or HCFA at any time when appropriate.

* Required only when decision is made to impose alternative remedies instead of or in addition to termination.

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BRIEF FOR THE CROSS-RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Whether cross-petitioner's pre-enforcement "void-for-vagueness" challenge to regulations governing the enforcement of Medicare and Medicaid nursing home standards is ripe for adjudication.

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In the Supreme Court of the United States

OCTOBER TERM, 1998

No. 98-1307

ILLINOIS COUNCIL ON LONG TERM CARE, INC.,
CROSS-PETITIONER

v.

DONNA E. SHALALA, SECRETARY OF HEALTH
AND HUMAN SERVICES, ET AL.

ON CROSS-PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF FOR THE CROSS-RESPONDENTS IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-12a[1]) is reported at 143 F.3d 1072. The opinion of the district court (Pet. App. 13a-21a) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on May 8, 1998. A petition for rehearing was denied on August 13, 1998 (Pet. App. 22a-23a). The Secretary of

[1] "Pet. App." refers to the Appendix to the petition for a writ of certiorari in *Shalala* v. *Illinois Council on Long Term Care, Inc.*, No. 98-1109 (filed Jan. 11, 1999).

Health and Human Services filed a petition for a writ of certiorari on January 11, 1999, which was docketed on January 12, 1999. Cross-petitioner filed a conditional cross-petition for a writ of certiorari on February 11, 1999. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The provisions of 42 U.S.C. 1395-i(3)(h) and 42 U.S.C. 1396r(h) are reproduced in the appendix to this brief, App., *infra*, 1a-20a. The provisions of 42 C.F.R. 488.301, 488.400-488.456, are also reproduced in the appendix to this brief, App., *infra*, 21a- 66a.

STATEMENT

To participate in Medicare and Medicaid, a nursing home must comply with standards designed to ensure resident beneficiary health and safety. 42 U.S.C. 1395i-3(a) to (d) (Medicare); 42 U.S.C. 1396r(a)-(d) (Medicaid). In this case, the court of appeals held that 42 U.S.C. 405(h), incorporated into the Medicare Act by 42 U.S.C. 1395ii, does not preclude cross-petitioner from bringing a pre-enforcement challenge to regulations issued by the Secretary of Health and Human Services to govern the enforcement of nursing home standards for Medicare. The Secretary has filed a petition for a writ of certiorari (No. 98-1109), asking this Court to review that decision. The cross-petition for a writ of certiorari asks this Court to decide a different question—whether cross-petitioner's void-for-vagueness challenge to certain Medicare and Medicaid regulations is ripe for constitutional adjudication.

1. The regulations cross-petitioner seeks to challenge as unconstitutionally vague were adopted pursuant to the Omnibus Budget Reconciliation Act of 1987

(1987 Act), Pub L. No. 100-203, 101 Stat. 1330. See 59 Fed. Reg. 56,116 (1994). Before the 1987 Act, the Medicare and Medicaid regulatory scheme governing nursing homes focused on theoretical capacity to provide care; evaluations were based on sources such as the provider's written policies and procedures, the qualifications of its staff, and the characteristics of its physical facilities. H.R. Rep. No. 391, 100th Cong., 1st Sess., pt. 1, at 466 (1987). Because Congress concluded that such a system did not adequately protect nursing home residents, it amended the Medicare and Medicaid statutes in 1987 to focus them on the adequacy of care actually delivered to individual residents, and to expand available enforcement remedies. *Id.* at 466-467; see also 42 U.S.C. 1395i-3(b)(2) (requiring facility to "attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident") (Medicare); 42 U.S.C. 1396r(b)(2) (same) (Medicaid); 42 C.F.R. 483.25 (declaring that "[e]ach resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with [a] comprehensive assessment and plan of care").

The resulting statute and implementing regulations set forth detailed requirements for patient admission, transfer, and discharge; the protection of resident rights; the scope and quality of health care and other services; the qualifications of the facility's staff and health care professionals; and the facility's physical environment. 42 C.F.R. 483.1-483.75. The statute also sets forth detailed procedures for ensuring compliance, including inspection and enforcement requirements. At intervals of no less than 15 months (and on average at least once a year), each skilled nursing facility is subject

to a standard survey that must be conducted without prior notice. 42 U.S.C. 1395i-3(g)(2)(A)(i) and (iii) (Medicare); 42 U.S.C. 1396r(g)(2)(A)(i) and (iii) (Medicaid). The survey must examine the quality of care furnished to a representative sample of patients, and must generally investigate the facility's compliance with statutory provisions protecting each resident's right to choose his or her attending physician, to be free from physical or chemical restraint, and to exercise other individual rights guaranteed by statute. 42 U.S.C. 1395i-3(g)(2)(A)(ii) (Medicare); 42 U.S.C. 1396r(g)(2)(A)(ii) (Medicaid); see also 42 C.F.R. 488.305.

Although surveys are generally under the control of state agencies, 42 U.S.C. 1395i-3(g)(1)(A) (Medicare); 42 U.S.C. 1396r(g)(1)(A) (Medicaid),[2] federal law requires that each survey be conducted by a multidisciplinary team of professionals following federally prescribed methods and procedures and using federally mandated forms. 42 U.S.C. 1395i-3(g)(2)(C) (Medicare); 42 U.S.C. 1396r(g)(2)(C) (Medicaid); see also 42 C.F.R. 488.26(c), 488.314. If the survey agency finds relatively

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[2] In Medicare, which is a federally administered program, the surveys are conducted pursuant to contracts with the State. See 42 U.S.C. 1395aa (1994 & Supp. II 1996), 1395i-3(g)(1)(A). In Medicaid, which is a "cooperative federalism" program jointly administered by the federal and state governments, the State must make provision for the conduct of the survey program as part of its "State plan." 42 U.S.C. 1396r(g)(1)(A). Although the States thus have principal responsibility for surveying nursing homes participating in either Medicare or Medicaid, the Secretary retains the authority to survey public nursing facilities operated by state, county, or municipal governments. The Secretary may also conduct a survey of *any* facility if she has reason to question the facility's compliance with the statute, 42 U.S.C. 1395i-3(g)(3)(D), 1396r(g)(3)(D), or if necessary to assess the state survey agency's performance, 42 U.S.C. 1395i-3(g)(3)(A), 1396r(g)(3)(A).

serious violations, *i.e.*, evidence that a nursing facility has provided "substandard quality of care,"[3] the agency must conduct a more extensive evaluation of the facility's operations and identify the policies and procedures that resulted in the deficiency. 42 U.S.C. 1395i-3(g)(2)(B) (Medicare); 42 U.S.C. 1396r(g)(2)(B) (Medicaid). Congress has required the Secretary and the States to make survey information available to the public, 42 U.S.C. 1395i-3(g)(5), 1396r(g)(5), and some survey information must be provided, as a matter of course, to certain state officials, licensing boards, and physicians. 42 C.F.R. 488.325.

Where deficiencies are detected, the pertinent regulatory agency must identify an appropriate remedy. 42 U.S.C. 1395i-3(h) (Medicare); 42 U.S.C. 1396r(h) (Medicaid).[4] Regulatory officials are empowered to direct a plan for correcting violations, to impose civil money penalties, to deny further reimbursement for services rendered after the deficiency is discovered, to appoint temporary management, to terminate a facility's right to participate in Medicare or Medicaid, or to transfer residents and close the facility. 42 U.S.C. 1395i-3(h)(2)

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[3] Substandard care is a relatively serious violation of the statutory requirements most directly related to the quality of care and the residents' quality of life. See 42 C.F.R. 488.301. By statute, any finding of substandard care must trigger a more detailed follow-up survey, and also results in an automatic, two-year loss of eligibility to conduct a nurse aide training program for facility employees. 42 U.S.C. 1395i-3(f)(2)(B)(iii) (Medicare); 42 U.S.C. 1396r(f)(2)(B)(iii) (Medicaid).

[4] In the federally-administered Medicare program, the state survey agency recommends an appropriate remedy and the Secretary makes the final decision. 42 U.S.C. 1395i-3(h)(1). In Medicaid, remedial powers are primarily vested in the State. 42 U.S.C. 1396r(h)(1).

(Medicare); 42 U.S.C. 1396r(h)(2) (Medicaid); 42 C.F.R. 488.406. Regulators are expected to use those enforcement mechanisms to "bring substandard facilities into compliance with [federal] quality of care requirements or to exclude them from the program." H.R. Rep. No. 391, *supra*, Pt. 1, at 452.

Congress also vested federal and state officials with substantial (but not unbridled) remedial discretion. The statute provides:

> The Secretary shall specify criteria, as to when and how each of such remedies is to be applied, the amounts of any fines, and the severity of each of these remedies * * *. Such criteria shall be designed so as to minimize the time between the identification of violations and final imposition of the remedies and shall provide for the imposition of incrementally more severe fines for repeated or uncorrected deficiencies.

42 U.S.C. 1395i-3(h)(2)(B) (Medicare); see also 42 U.S.C. 1396r(h)(2)(A) (Medicaid). Pursuant to that mandate, the Secretary has promulgated regulations that calibrate the enforcement remedy to the scope and severity of the nursing home's deficiencies. 42 C.F.R. 488.400-488.430. In particular, the choice of remedies depends on the degree of actual or potential harm to resident health or safety, and the extent to which the identified deficiencies reflect isolated occurrences or pervasive problems. 42 C.F.R. 488.404, 488.408. For example, regulators will not impose any remedy if they conclude that a nursing home "substantially" complies with statutory requirements, *i.e.*, if the care, though technically falling short of a statutory standard, has not resulted in any harm to residents and poses no more than a risk of minimal harm in the future. 42 C.F.R.

488.301, 488.408(f)(2). More serious violations, such as those that have resulted in actual harm to a resident or that are sufficiently widespread or serious to have the potential to cause more than minimal harm, may result in significant sanctions, including civil money penalties or the denial of payment for new nursing home admissions. 42 C.F.R. 488.408(d). And violations that place the health or safety of residents in immediate jeopardy may result in the appointment of temporary management, closure of the facility, or termination of the facility's right to participate in Medicare or Medicaid. 42 C.F.R. 488.408(e).

2. Cross-petitioner Illinois Council on Long Term Care, Inc., a trade association of nursing facilities in Illinois, filed a complaint challenging the Secretary's regulations concerning enforcement of Medicare and Medicaid nursing home standards, and objecting to certain provisions of a manual that is used in surveying nursing care facilities. Cross-petitioner alleged that the regulatory standards governing the imposition of nursing home remedies are unconstitutionally vague; that they exceed the Secretary's statutory authority; that they violate the Due Process Clause by failing to provide a constitutionally adequate opportunity to contest enforcement actions; and that the manual used in the implementation of the survey and inspection program was improperly promulgated without use of the "notice and comment" rulemaking procedures provided by 5 U.S.C. 553.

The district court dismissed the complaint for lack of subject matter jurisdiction. Pet. App. 13a-21a. Cross-petitioner could not rest jurisdiction on 42 U.S.C. 405(g) (as incorporated by 42 U.S.C. 1395cc(h)) because it had not exhausted applicable administrative remedies. Nor could cross-petitioner obtain jurisdiction by relying on

28 U.S.C. 1331 or 1346 instead, because 42 U.S.C. 405(h) bars federal courts from asserting jurisdiction under those provisions. Pet. App. 15a-19a.

3. The court of appeals reversed in part and affirmed in part. Pet. App. 1a-12a. As explained in greater detail in the Secretary's petition for a writ of certiorari in No. 98-1109 (at 7-8), the court of appeals held that 42 U.S.C. 405(h) does not preclude federal courts from exercising general federal question jurisdiction (pursuant to 28 U.S.C. 1331 and 1346) over non-monetary claims arising under the Medicare or Medicaid Programs, including cross-petitioner's claims for pre-enforcement review of Medicare regulations. Nonetheless, the court of appeals affirmed dismissal of most of cross-petitioner's claims on alternative grounds.

As relevant here, the court of appeals held that cross-petitioner's challenge to the Secretary's regulations on vagueness grounds is not ripe for judicial review. Pet. App. 10a-11a. Vagueness challenges which do not involve First Amendment freedoms, the court of appeals reasoned, must be based on a specific application of the law to the plaintiff; they may not be based on the alleged vagueness of the law as applied to the conduct of others. *Id.* at 10a. Such challenges therefore must be brought and adjudicated "in the light of the facts of the case at hand." *Ibid.* (quoting *United States* v. *Mazurie*, 419 U.S. 544, 550 (1975)).

Cross-petitioner, the court of appeals observed, had sought to avoid the jurisdictional limitations of 42 U.S.C. 405(h) by framing its pre-enforcement challenge as a facial attack on the validity of the agency's regulations, a highly abstract claim. Because cross-petitioner had chosen to frame its attack in such general terms—rather than await and challenge a specific application of the regulations—cross-petitioner "finds

itself with no 'facts of the case at hand' and therefore without any hope of success on a claim that the regulations are unconstitutionally vague." Pet. App. 10a. Accordingly, the court of appeals held that cross-petitioner's vagueness challenge is not ripe for decision and had been properly dismissed. *Id.* at 11a.

ARGUMENT

The decision below correctly applies well-established ripeness principles to cross-petitioner's void-for-vagueness claim. The case-specific holding challenged by cross-petitioner is consistent with this Court's precedents, does not conflict with other appellate decisions, and does not otherwise raise any issue of exceptional importance. It is, moreover, separate and discrete from the statutory jurisdictional issue raised by the Secretary's petition for a writ of certiorari in No. 98-1109. Consequently, the Secretary's petition—which cross-petitioner agrees should be granted, 98-1109 Br. in Opp. at 16—can be fully adjudicated without considering the ripeness issue presented in the conditional cross-petition.

1. The ripeness doctrine has its origins both in Article III and in judicially-developed rules governing the exercise of jurisdiction. *Reno* v. *Catholic Social Servs., Inc.*, 509 U.S. 43, 57 n.18 (1993). At its core, the doctrine is designed "to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Abbott Labs.* v. *Gardner*, 387 U.S. 136, 148-149 (1967). Accordingly, in deciding whether or not an agency's decision is ripe for

judicial review, the Court has examined both the "fitness of the issues for judicial decision" and the "hardship to the parties of withholding court consideration." *Id.* at 149; *Ohio Forestry Ass'n* v. *Sierra Club*, 118 S. Ct. 1665, 1670 (1998).

a. Under those established standards, cross-petitioner's void-for-vagueness claim is premature. The essence of a void-for-vagueness claim is that the challenged criminal or regulatory prohibition fails to articulate standards with sufficient clarity to permit the claimant to conform his conduct to law. See *Grayned* v. *City of Rockford*, 408 U.S. 104, 108 (1972) ("[B]ecause we assume that man is free to steer between lawful and unlawful conduct, we insist that laws give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly."). "A plaintiff who engages in some conduct that is clearly proscribed," however, "cannot complain of the vagueness of the law as applied to the conduct of others." *Village of Hoffman Estates* v. *Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 495 (1982). As a result, a vagueness challenge that is not based on the First Amendment must identify the claimant's specific conduct (the propriety of which is allegedly unclear), and the court must "examine the complainant's conduct before analyzing other hypothetical applications of the law." *Ibid.* Thus, "[v]agueness challenges to statutes which do not involve First Amendment freedoms must be examined in the light of the facts of the case at hand." *Id.* at 495 n.7 (quoting *United States* v. *Mazurie*, 419 U.S. 544, 550 (1975)).

Because cross-petitioner's vagueness challenge neither involves First Amendment freedoms, nor arises out of a specific set of facts—indeed, it does not even identify the specific conduct in which cross-petitioner or

its members propose to engage—it is not currently "fit" for judicial review. See, *e.g.*, *Catholic Social Servs.*, 509 U.S. at 58-59 (mere passage of statute and issuance of regulations do not give complainant a ripe claim absent agency action "applying the regulation to him"); *Lujan* v. *National Wildlife Fed'n*, 497 U.S. 871, 891 (1990) ("[A] regulation is not ordinarily considered the type of agency action 'ripe' for judicial review under the APA until the scope of the controversy has been reduced to more manageable proportions, and its factual components fleshed out, by some concrete action applying the regulation to the claimant's situation in a fashion that harms or threatens to harm him."). Thus, this is not a case involving a "formalized" administrative decision the "effects" of which have been "felt in a concrete way by the challenging part[y]." *Abbott Labs.*, 387 U.S. at 148-149. It is instead an anticipatory challenge seeking generalized review of regulations outside of the context of a specific application. For that reason, cross-petitioner is incorrect to assert that requiring it and its members to await and challenge specific applications of the regulations amounts to a "heightened" pleading requirement. See Cross-Pet. 12-13. The question is not one of pleading; it is a question of timing. Under fundamental principles of justiciability, only challenges to specific and identifiable applications of the allegedly vague regulations—and not the general and highly abstract allegation that the pertinent standards are unclear—are "fit[] for judicial decision." *Abbott Labs.*, 387 U.S. at 149.

b. Nor can cross-petitioner show that the "hardship" of "withholding court consideration" weighs in favor of immediate, pre-enforcement review. Indeed, cross-petitioner cannot show that "withholding * * * consideration" of its challenge will cause it or its

members any "hardship" at all. *Abbott Labs.*, 387 U.S. at 149. This is not a case in which cross-petitioner or its members will be forced, as a result of vague regulatory standards, to change their conduct or face a severe penalty. See *Lujan*, 497 U.S. at 891 (rules requiring the complainant "to adjust [its] conduct immediately" may be ripe); *Catholic Social Servs.*, 509 U.S. at 58 (challenge to regulation not ripe where "the impact" of the regulation cannot "be said to be felt immediately by those subject to it in conducting their day-to-day affairs") (internal quotation marks omitted). To the contrary, cross-petitioner does not challenge any conduct-governing standards at all. Instead, it limits its void-for-vagueness challenge to the regulations governing the *penalty or remedy* that will be imposed once a violation is discovered.

Petitioner thus disavows any challenge to the extensive and detailed regulations applicable to the day-to-day operation of its members' facilities.[5] Instead, it focuses the vagueness attack solely on the scope and severity factors that are used to determine the appropriate remedy for an actual violation. See Amended Compl. ¶¶ 43-50; Cross-Pet. 3-5. Cross-petitioner, for example, alleges that the term "substantial compliance," which is the standard that must be met before no penalty will be imposed despite the existence of some violations, is unconstitutionally vague, see Amended Compl. ¶ 43A;[6] and it likewise challenges the adequacy

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[5] See Cross-Pet. C.A. Br. 3 (cross-petitioner "does not seek to overturn or modify the new health, safety, and resident rights standards" established by the 1987 statutory amendments); Amended Compl. ¶ 1 (similar).

[6] "Substantial compliance" is defined as "a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than

of the definition of the term "substandard quality of care," which is a condition that, if found, will result in additional investigations and more severe penalties, see *id.* ¶ 43B.[7] As the Amended Complaint summarizes, cross-petitioner claims that relevant legal sources do not "provide [its] members with any meaningful guidance for determining whether their conduct is in 'substantial compliance,'"—which would permit them to avoid penalties despite actual violations—"or for distinguishing between deficiencies which result in a finding of 'substandard quality of care,' and those which trigger lesser findings and enforcement penalties." *Id.* ¶ 46. See also *id.* ¶ 44 (alleging that terms such as "actual harm," "minimal harm," "isolated," "pattern," and "widespread," which are used to define "substantial compliance" and "substandard quality of care," are unduly vague). Uncertainty as to the remedies that will be used to ensure compliance with lawful substantive standards, however, is not the sort of undue hardship that warrants pre-enforcement review. Cf. *Texas* v. *United States*, 118 S. Ct. 1257, 1259-1260 (1998); *Toilet Goods Ass'n* v. *Gardner*, 387 U.S. 158, 163-164 (1967).

c. Seeking to avoid that result, cross-petitioner asserts (at 10-11) that a "systemic" challenge to the

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the potential for causing minimal harm." 42 C.F.R. 488.301; Amended Compl. ¶ 43A.

[7] "Substandard quality of care" is defined as "one or more deficiencies related to [certain] participation requirements" that (1) "[create] immediate jeopardy to resident health or safety," (2) "[constitute] a pattern of or widespread actual harm that is not immediate jeopardy," or (3) "[engender] widespread potential for more than minimal harm, but less than immediate jeopardy, [where] no actual harm" has yet occurred. 42 C.F.R. 488.301; Amended Compl. ¶ 43B.

entire regulatory regime can be brought before the regulations are applied and enforced in a concrete setting. The ordinary rule, however, is that a regulation is not considered "ripe" for judicial review under the Administrative Procedure Act (APA) until it has been applied to a particular claimant and its effects are manifested in a concrete way. *Lujan*, 497 U.S. at 891. As this Court has explained:

> The case-by-case approach that this requires is understandably frustrating to an organization such as respondent, which has as its objective across-the-board protection * * *. But this is the traditional, and remains the normal, mode of operation of the courts. Except where Congress explicitly provides for our correction of the administrative process at a higher level of generality, we intervene in the administration of the laws only when, and to the extent that, a specific "final agency action" has an actual or immediately threatened effect.

Id. at 894.[8]

Alternatively, cross-petitioner argues that its vagueness challenge should be considered "fit" for review now because administrative review would not improve the "fitness" of the issues it seeks to raise. In particular, cross-petitioner argues that administrative review will add little because administrative law judges cannot pass upon the validity of the regulations or overturn the choice of enforcement remedy. Cross-Pet. 5, 9-10,

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[8] Congress may, by statute, specifically provide for immediate review of a regulation to further interests in national uniformity or prompt resolution of a disputed matter. See, *e.g.*, *Harrison* v. *PPG Indus.*, 446 U.S. 578, 592-593 (1980). Congress has not done so here.

12. Contrary to cross-petitioner's claim, an administrative record will demonstrate how the Secretary or state enforcement officials are tailoring enforcement remedies to the particular facts of the case, and may well document the enforcement agency's reasons and justifications for imposing the chosen sanction or corrective action, significantly aiding judicial review. Cf. *Toilet Goods Ass'n*, 387 U.S. at 163-164; *Ohio Forestry Ass'n*, 118 S. Ct. at 1671-1672.

Finally, cross-petitioner asserts that it might be able to render its claims more concrete by "provid[ing] multiple examples of how the regulations have been randomly applied against its members." Cross-Pet. 12. That proposal, however, is likewise foreclosed by this Court's precedents:

> [I]t is at least entirely certain that the flaws in the entire "program"—consisting principally of the many individual actions referenced in the complaint, and presumably actions yet to be taken as well—cannot be laid before the courts for wholesale correction under the APA, simply because one of them that is ripe for review adversely affects one of respondent's members.

Lujan, 497 U.S. at 892-893. Simply put, if any of cross-petitioner's members is aggrieved by a specific application of the regulations, then its individual claim may be ripe for judicial review and may be brought once statutory exhaustion requirements are met. But that does not make the myriad potential (and as of now, purely hypothetical) future applications of the regulatory scheme ripe for immediate pre-enforcement review.

2. Nor is the question presented in the cross-petition related to, or necessary to, the resolution of the ques-

tion presented in the Secretary's petition for a writ of certiorari in No. 98-1109.

The Secretary's petition seeks review of whether 42 U.S.C. 405(h), as incorporated into the Medicare Act by 42 U.S.C. 1395ii, prevents federal courts from asserting general federal question jurisdiction over any part of cross-petitioner's pre-enforcement challenge to the Secretary's Medicare nursing home regulations. That question is analytically distinct from the question on which cross-petitioner seeks review, which is whether its void-for-vagueness challenge is sufficiently concrete to be "fit[] for judicial decision," in light of any "hardship" that might result from withholding review. See *Abbott Labs.*, 387 U.S. at 149. The former is a question of statutory construction; the latter is an application of the criteria this Court articulated in *Abbott Laboratories.*[9]

Notwithstanding the facial dissimilarity of the two issues, cross-petitioner asserts that this Court's decision in *Reno* v. *Catholic Social Services, Inc.*, *supra*, demonstrates them to be related. Cross-petitioner is mistaken. That case concerned an Immigration and Naturalization Service (INS) policy that ostensibly called for INS personnel to reject some aliens' applications for legalization before the aliens even filed them —a practice called "front-desking," because the applica-

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[9] Of course, the ripeness doctrine and the statutory provisions governing judicial review may both point toward postponing judicial review until the Secretary's policies are applied in a concrete setting. But whether Congress has chosen to delay judicial review and channel it through certain mechanisms under Section 405(h), as it has plenary authority to do, see *Weinberger* v. *Salfi*, 422 U.S. 749, 762 (1975), is a separate question from whether a particular claim meets the constitutional and prudential requirements for justiciability.

tion would be rejected at the front desk of the INS office. The Court held that any alien subjected to that practice had a "ripe" claim. Such an alien had been subjected to the effects of the INS's substantive policy in a concrete and adverse manner (thus enhancing the fitness of the issue for judicial review); and, because the otherwise exclusive mechanism for review did not apply to aliens who had never filed an application, withholding review would leave such an alien without any means for obtaining judicial review (making the hardship of withholding review severe). See *Catholic Social Servs.*, 509 U.S. at 61-63. Indeed, declaring the claim to be "unripe," the Court concluded, would contravene the presumption that Congress generally intends judicial review to be available. *Ibid.*

Here, cross-petitioner's claim is decidedly unripe, and the construction of Section 405(h) at issue in the Secretary's petition for a writ of certiorari in No. 98-1109 will not alter that conclusion. Whether or not Section 405(h) requires claims like cross-petitioner's to be channeled through the administrative process established by the Medicare Act, cross-petitioner's current vagueness claim is too abstract because, rather than challenging a specific and concrete application of the regulations to a particular entity, it launches a broad attack based on an alleged lack of clarity overall. Likewise, even if Section 405(h) requires presentment of such claims and exhaustion of administrative remedies under Section 405(g), as the Secretary contends in her petition for a writ of certiorari in No. 98-1109 (at 10-14), any party aggrieved by a specific application of the regulations will be able to obtain judicial review after such presentment and exhaustion occurs. See 98-1109 Pet. at 3-4 & n.4; 98-1109 Reply Br. at 8-9 n.4. The resolution of the question presented in No. 98-1109 thus

will not alter the ripeness analysis that cross-petitioner asks this Court to address.[10]

3. Finally, also relying on *Catholic Social Services*, cross-petitioner argues (at 12-13) that the court of appeals erred in failing to remand for further factual development. There are, however, no further material facts to be developed. In *Catholic Social Services*, there was no record evidence demonstrating that the challenged practice of "front-desking" in fact had been applied to any member of the plaintiff class. "[B]ecause * * * the front-desking of a particular class member is not only sufficient to make [a class-member's] legal claims ripe, but necessary to do so," the Court found it appropriate to "remand * * * for proceedings to determine which class members were front-desked." 509 U.S. at 66-67.

Here, in contrast, there is no doubt that the regulations at issue have been applied to some of cross-petitioner's members. The only question is whether cross-petitioner may bring an immediate and across-the-board pre-enforcement challenge to the regulations on the grounds that they are unclear, or whether any challenge to those regulations should instead be raised in the context of a specific and concrete application. The answer to that question does not require further fact-finding by the district court, and has been provided

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[10] The opportunity for judicial review exists even if some of cross-petitioner's claims are not ones that the agency itself would adjudicate in the first instance, since judicial review will still be available after presentment and exhaustion. Cf. *Weinberger*, 422 U.S. at 760-762 (challenge to constitutionality of a provision of Medicare Act, which cannot be resolved in the administrative process, must be brought through administrative process and cannot be subject of pre-enforcement action under 28 U.S.C. 1331).

by the court of appeals in accordance with legal principles established in this Court's decisions.

CONCLUSION

For the foregoing reasons, the conditional cross-petition for a writ of certiorari should be denied, without regard to the disposition of the Secretary's petition for a writ of certiorari in No. 98-1109.

Respectfully submitted.

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APPENDIX

1. Section 1395-i(3)(h) of Title 42, United States Code, provides:

(h) Enforcement process

(1) In general

If a State finds, on the basis of a standard, extended, or partial extended survey under subsection (g)(2) of this section or otherwise, that a skilled nursing facility no longer meets a requirement of subsection (b), (c), or (d) of this section, and further finds that the facility's deficiencies—

(A) immediately jeopardize the health or safety of its residents, the State shall recommend to the Secretary that the Secretary take such action as described in paragraph (2)(A)(i); or

(B) do not immediately jeopardize the health or safety of its residents, the State may recommend to the Secretary that the Secretary take such action as described in paragraph (2)(A)(ii).

If a State finds that a skilled nursing facility meets the requirements of subsections (b), (c), and (d) of this section, but, as of a previous period, did not meet such requirements, the State may recommend a civil money penalty under paragraph (2)(B)(ii) for the days in which it finds that the facility was not in compliance with such requirements.

(2) Secretarial authority

(A) In general

With respect to any skilled nursing facility in a State, if the Secretary finds, or pursuant to a recommendation of the State under paragraph (1) finds, that a skilled nursing facility no longer meets a requirement of subsection (b), (c), (d), or (e) of this section, and further finds that the facility's deficiencies—

(i) immediately jeopardize the health or safety of its residents, the Secretary shall take immediate action to remove the jeopardy and correct the deficiencies through the remedy specified in subparagraph (B)(iii), or terminate the facility's participation under this subchapter and may provide, in addition, for one or more of the other remedies described in subparagraph (B); or

(ii) do not immediately jeopardize the health or safety of its residents, the Secretary may impose any of the remedies described in subparagraph (B).

Nothing in this subparagraph shall be construed as restricting the remedies available to the Secretary to remedy a skilled nursing facility's deficiencies. If the Secretary finds, or pursuant to the recommendation of the State under paragraph (1) finds, that a skilled nursing facility meets such requirements but, as of a previous period, did not meet such requirements, the Secretary may provide for a civil money penalty under subparagraph (B)(ii) for the days on which he finds that the facility was not in compliance with such requirements.

(B) Specified remedies

The Secretary may take the following actions with respect to a finding that a facility has not met an applicable requirement.

(i) Denial of payment

The Secretary may deny any further payments under this subchapter with respect to all individuals entitled to benefits under this subchapter in the facility or with respect to such individuals admitted to the facility after the effective date of the finding.

(ii) Authority with respect to civil money penalties

The Secretary may impose a civil money penalty in an amount not to exceed $10,000 for each day of noncompliance. The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(iii) Appointment of temporary management

In consultation with the State, the Secretary may appoint temporary management to oversee the operation of the facility and to assure the health and safety of the facility's residents, where there is a need for temporary management while—

(I) there is an orderly closure of the facility, or

(II) improvements are made in order to bring the facility into compliance with all the requirements of subsections (b), (c), and (d) of this section.

The temporary management under this clause shall not be terminated under subclause (II) until the Secretary has determined that the facility has the management capability to ensure continued compliance with all the requirements of subsections (b), (c), and (d).

The Secretary shall specify criteria, as to when and how each of such remedies is to be applied, the amounts of any fines, and the severity of each of these remedies, to be used in the imposition of such remedies. Such criteria shall be designed so as to minimize the time between the identification of violations and final imposition of the remedies and shall provide for the imposition of incrementally more severe fines for repeated or uncorrected deficiencies. In addition, the Secretary may provide for other specified remedies, such as directed plans of correction.

(C) Continuation of payments pending remediation

The Secretary may continue payments, over a period of not longer than 6 months after the effective date of the findings, under this subchapter with respect to a skilled nursing facility not in compliance with a requirement of subsection (b), (c), or (d) of this section, if—

(i) the State survey agency finds that it is more appropriate to take alternative action to assure compliance of the facility with the requirements than to terminate the certification of the facility,

(ii) the State has submitted a plan and timetable for corrective action to the Secretary for approval and the Secretary approves the plan of corrective action, and

(iii) the facility agrees to repay to the Federal Government payments received under this subparagraph if the corrective action is not taken in accordance with the approved plan and timetable.

The Secretary shall establish guidelines for approval of corrective actions requested by States under this subparagraph.

(D) Assuring prompt compliance

If a skilled nursing facility has not complied with any of the requirements of subsections (b), (c), and (d) of this section, within 3 months after the date the facility is found to be out of compliance with such requirements, the Secretary shall impose the remedy described in subparagraph (B)(i) for all individuals who are admitted to the facility after such date.

(E) Repeated noncompliance

In the case of a skilled nursing facility which, on 3 consecutive standard surveys conducted under subsection (g)(2) of this section, has been found to have provided substandard quality of care, the Secretary shall (regardless of what other remedies are provided)—

(i) impose the remedy described in subparagraph (B)(i), and

(ii) monitor the facility under subsection (g)(4)(B) of this section,

until the facility has demonstrated, to the satisfaction of the Secretary, that it is in compliance with the requirements of subsections (b), (c), and (d) of this section, and that it will remain in compliance with such requirements.

(3) Effective period of denial of payment

A finding to deny payment under this subsection shall terminate when the Secretary finds that the facility is in substantial compliance with all the requirements of subsections (b), (c), and (d) of this section.

(4) Immediate termination of participation for facility where Secretary finds noncompliance and immediate jeopardy

If the Secretary finds that a skilled nursing facility has not met a requirement of subsection (b), (c), or (d) of this section, and finds that the failure immediately jeopardizes the health or safety of its residents, the Secretary shall take immediate action to remove the jeopardy and correct the deficiencies through the remedy specified in paragraph (2)(B)(iii), or the Secretary shall terminate the facility's participation under this subchapter. If the facility's participation under this subchapter is terminated, the State shall provide for the safe and orderly transfer of the residents eligible under this subchapter consistent with the requirements of subsection (c)(2) of this section.

(5) Construction

The remedies provided under this subsection are in addition to those otherwise available under State or Federal law and shall not be construed as limiting such other remedies, including any remedy available to an individual at common law. The remedies described in clauses (i),[4] and (iii) of paragraph (2)(B) may be imposed during the pendency of any hearing.

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[4] So in original. The comma probably should not appear.

(6) Sharing of information

Notwithstanding any other provision of law, all information concerning skilled nursing facilities required by this section to be filed with the Secretary or a State agency shall be made available by such facilities to Federal or State employees for purposes consistent with the effective administration of programs established under this subchapter and subchapter XIX of this chapter, including investigations by State medicaid fraud control units.

(i) Construction

Where requirements or obligations under this section are identical to those provided under section 1396r of this title, the fulfillment of those requirements or obligations under section 1396r of this title shall be considered to be the fulfillment of the corresponding requirements or obligations under this section.

2. Section 1396r(h) of Title 42, United States Code, provides:

(h) Enforcement process

(1) In general

If a State finds, on the basis of a standard, extended, or partial extended survey under subsection (g)(2) of this section or otherwise, that a nursing facility no longer meets a requirement of subsection (b), (c), or (d) of this section, and further finds that the facility's deficiencies—

(A) immediately jeopardize the health or safety of its residents, the State shall take immediate action to remove the jeopardy and correct the deficiencies through the remedy specified in paragraph (2)(A)(iii), or terminate the facility's participation under the State plan and may provide, in addition, for one or more of the other remedies described in paragraph (2); or

(B) do not immediately jeopardize the health or safety of its residents, the State may—

(i) terminate the facility's participation under the State plan,

(ii) provide for one or more of the remedies described in paragraph (2), or

(iii) do both.

Nothing in this paragraph shall be construed as restricting the remedies available to a State to remedy a nursing facility's deficiencies. If a State finds that a nursing facility meets the requirements of subsections (b), (c), and (d) of this section, but, as of a previous

period, did not meet such requirements, the State may provide for a civil money penalty under paragraph (2)(A)(ii) for the days in which it finds that the facility was not in compliance with such requirements.

(2) Specified remedies

(A) Listing

Except as provided in subparagraph (B)(ii), each State shall establish by law (whether statute or regulation) at least the following remedies:

(i) Denial of payment under the State plan with respect to any individual admitted to the nursing facility involved after such notice to the public and to the facility as may be provided for by the State.

(ii) A civil money penalty assessed and collected, with interest, for each day in which the facility is or was out of compliance with a requirement of subsection (b), (c), or (d) of this section. Funds collected by a State as a result of imposition of such a penalty (or as a result of the imposition by the State of a civil money penalty for activities described in subsections (b)(3)(B)(ii)(I), (b)(3)(B)(ii)(II), or (g)(2)(A)(i) of this section) shall be applied to the protection of the health or property of residents of nursing facilities that the State or the Secretary finds deficient, including payment for the costs of relocation of residents to other facilities, maintenance of operation of a facility pending correction of deficiencies or closure, and reimbursement of residents for personal funds lost.

(iii) The appointment of temporary management to oversee the operation of the facility and to assure

the health and safety of the facility's residents, where there is a need for temporary management while—

(I) there is an orderly closure of the facility, or

(II) improvements are made in order to bring the facility into compliance with all the requirements of subsections (b), (c), and (d) of this section.

The temporary management under this clause shall not be terminated under subclause (II) until the State has determined that the facility has the management capability to ensure continued compliance with all the requirements of subsections (b), (c), and (d) of this section.

(iv) The authority, in the case of an emergency, to close the facility, to transfer residents in that facility to other facilities, or both.

The State also shall specify criteria, as to when and how each of such remedies is to be applied, the amounts of any fines, and the severity of each of these remedies, to be used in the imposition of such remedies. Such criteria shall be designed so as to minimize the time between the identification of violations and final imposition of the remedies and shall provide for the imposition of incrementally more severe fines for repeated or uncorrected deficiencies. In addition, the State may provide for other specified remedies, such as directed plans of correction.

(B) Deadline and guidance

(i) Except as provided in clause (ii), as a condition for approval of a State plan for calendar quarters beginning on or after October 1, 1989, each State shall establish the remedies described in clauses (i) through (iv) of subparagraph (A) by not later than October 1, 1989. The Secretary shall provide, through regulations by not later than October 1, 1988, guidance to States in establishing such remedies; but the failure of the Secretary to provide such guidance shall not relieve a State of the responsibility for establishing such remedies.

(ii) A State may establish alternative remedies (other than termination of participation) other than those described in clauses (i) through (iv) of subparagraph (A), if the State demonstrates to the Secretary's satisfaction that the alternative remedies are as effective in deterring noncompliance and correcting deficiencies as those described in subparagraph (A).

(C) Assuring prompt compliance

If a nursing facility has not complied with any of the requirements of subsections (b), (c), and (d) of this section, within 3 months after the date the facility is found to be out of compliance with such requirements, the State shall impose the remedy described in subparagraph (A)(i) for all individuals who are admitted to the facility after such date.

(D) Repeated noncompliance

In the case of a nursing facility which, on 3 consecutive standard surveys conducted under subsection (g)(2) of this section, has been found to have provided substandard quality of care, the State shall (regardless of what other remedies are provided)—

(i) impose the remedy described in subparagraph (A)(i), and

(ii) monitor the facility under subsection (g)(4)(B) of this section,

until the facility has demonstrated, to the satisfaction of the State, that it is in compliance with the requirements of subsections (b), (c), and (d) of this section, and that it will remain in compliance with such requirements.

(E) Funding

The reasonable expenditures of a State to provide for temporary management and other expenses associated with implementing the remedies described in clauses (iii) and (iv) of subparagraph (A) shall be considered, for purposes of section 1396b(a)(7) of this title, to be necessary for the proper and efficient administration of the State plan.

(F) Incentives for high quality care

In addition to the remedies specified in this paragraph, a State may establish a program to reward, through public recognition, incentive payments, or both, nursing facilities that provide the highest quality care to residents who are entitled to medical

assistance under this subchapter. For purposes of section 1396b(a)(7) of this title, proper expenses incurred by a State in carrying out such a program shall be considered to be expenses necessary for the proper and efficient administration of the State plan under this subchapter.

(3) Secretarial authority

(A) For State nursing facilities

With respect to a State nursing facility, the Secretary shall have the authority and duties of a State under this subsection, including the authority to impose remedies described in clauses (i), (ii), and (iii) of paragraph (2)(A).

(B) Other nursing facilities

With respect to any other nursing facility in a State, if the Secretary finds that a nursing facility no longer meets a requirement of subsection (b), (c), (d), or (e) of this section, and further finds that the facility's deficiencies—

(i) immediately jeopardize the health or safety of its residents, the Secretary shall take immediate action to remove the jeopardy and correct the deficiencies through the remedy specified in subparagraph (C)(iii), or terminate the facility's participation under the State plan and may provide, in addition, for one or more of the other remedies described in subparagraph (C); or

(ii) do not immediately jeopardize the health or safety of its residents, the Secretary

may impose any of the remedies described in subparagraph (C).

Nothing in this subparagraph shall be construed as restricting the remedies available to the Secretary to remedy a nursing facility's deficiencies. If the Secretary finds that a nursing facility meets such requirements but, as of a previous period, did not meet such requirements, the Secretary may provide for a civil money penalty under subparagraph (C)(ii) for the days on which he finds that the facility was not in compliance with such requirements.

(C) Specified remedies

The Secretary may take the following actions with respect to a finding that a facility has not met an applicable requirement:

(i) Denial of payment

The Secretary may deny any further payments to the State for medical assistance furnished by the facility to all individuals in the facility or to individuals admitted to the facility after the effective date of the finding.

(ii) Authority with respect to civil money penalties

The Secretary may impose a civil money penalty in an amount not to exceed $10,000 for each day of noncompliance. The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a

penalty or proceeding under section 1320a-7a(a) of this title.

(iii) Appointment of temporary management

In consultation with the State, the Secretary may appoint temporary management to oversee the operation of the facility and to assure the health and safety of the facility's residents, where there is a need for temporary management while—

(I) there is an orderly closure of the facility, or

(II) improvements are made in order to bring the facility into compliance with all the requirements of subsections (b), (c), and (d) of this section.

The temporary management under this clause shall not be terminated under subclause (II) until the Secretary has determined that the facility has the management capability to ensure continued compliance with all the requirements of subsections (b), (c), and (d) of this section.

The Secretary shall specify criteria, as to when and how each of such remedies is to be applied, the amounts of any fines, and the severity of each of these remedies, to be used in the imposition of such remedies. Such criteria shall be designed so as to minimize the time between the identification of violations and final imposition of the remedies and shall provide for the imposition of incrementally more severe fines for repeated or uncorrected deficiencies. In addition, the Secretary may provide

for other specified remedies, such as directed plans of correction.

(D) Continuation of payments pending remediation

The Secretary may continue payments, over a period of not longer than 6 months after the effective date of the findings, under this subchapter with respect to a nursing facility not in compliance with a requirement of subsection (b), (c), or (d) of this section, if—

(i) the State survey agency finds that it is more appropriate to take alternative action to assure compliance of the facility with the requirements than to terminate the certification of the facility, and

(ii) the State has submitted a plan and timetable for corrective action to the Secretary for approval and the Secretary approves the plan of corrective action.

(iii) Repealed. Pub.L. 105-33, Title IV, § 4754(a)(3), Aug. 5, 1997, 111 Stat. 526

The Secretary shall establish guidelines for approval of corrective actions requested by States under this subparagraph.

(4) Effective period of denial of payment

A finding to deny payment under this subsection shall terminate when the State or Secretary (or both, as the case may be) finds that the facility is in substantial compliance with all the requirements of subsections (b), (c), and (d) of this section.

(5) Immediate termination of participation for facility where State or Secretary finds non-compliance and immediate jeopardy

If either the State or the Secretary finds that a nursing facility has not met a requirement of subsection (b), (c), or (d) of this section, and finds that the failure immediately jeopardizes the health or safety of its residents, the State or the Secretary, respectively[5] shall notify the other of such finding, and the State or the Secretary, respectively, shall take immediate action to remove the jeopardy and correct the deficiencies through the remedy specified in paragraph (2)(A)(iii) or (3)(C)(iii), or terminate the facility's participation under the State plan. If the facility's participation in the State plan is terminated by either the State or the Secretary, the State shall provide for the safe and orderly transfer of the residents eligible under the State plan consistent with the requirements of subsection (c)(2) of this section.

(6) Special rules where State and Secretary do not agree on finding of noncompliance

(A) State finding of noncompliance and no Secretarial finding of noncompliance

If the Secretary finds that a nursing facility has met all the requirements of subsections (b), (c), and (d) of this section, but a State finds that the facility has not met such requirements and the failure does not immediately jeopardize the health or safety of its residents, the State's findings shall control and the remedies imposed by the State shall be applied.

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[5] So in original. Probably should be followed by a comma.

(B) Secretarial finding of noncompliance and no State finding of noncompliance

If the Secretary finds that a nursing facility has not met all the requirements of subsections (b), (c), and (d) of this section, and that the failure does not immediately jeopardize the health or safety of its residents, but the State has not made such a finding, the Secretary—

(i) may impose any remedies specified in paragraph (3)(C) with respect to the facility, and

(ii) shall (pending any termination by the Secretary) permit continuation of payments in accordance with paragraph (3)(D).

(7) Special rules for timing of termination of participation where remedies overlap

If both the Secretary and the State find that a nursing facility has not met all the requirements of subsections (b), (c), and (d) of this section, and neither finds that the failure immediately jeopardizes the health or safety of its residents—

(A)(i) if both find that the facility's participation under the State plan should be terminated, the State's timing of any termination shall control so long as the termination date does not occur later than 6 months after the date of the finding to terminate;

(ii) if the Secretary, but not the State, finds that the facility's participation under the State plan should be terminated, the Secretary shall (pending any

termination by the Secretary) permit continuation of payments in accordance with paragraph (3)(D); or

(iii) if the State, but not the Secretary, finds that the facility's participation under the State plan should be terminated, the State's decision to terminate, and timing of such termination, shall control; and

(B)(i) if the Secretary or the State, but not both, establishes one or more remedies which are additional or alternative to the remedy of terminating the facility's participation under the State plan, such additional or alternative remedies shall also be applied, or

(ii) if both the Secretary and the State establish one or more remedies which are additional or alternative to the remedy of terminating the facility's participation under the State plan, only the additional or alternative remedies of the Secretary shall apply.

(8) Construction

The remedies provided under this subsection are in addition to those otherwise available under State or Federal law and shall not be construed as limiting such other remedies, including any remedy available to an individual at common law. The remedies described in clauses (i), (iii), and (iv) of paragraph (2)(A) may be imposed during the pendency of any hearing. The provisions of this subsection shall apply to a nursing facility (or portion thereof) notwithstanding that the facility (or portion thereof) also is a skilled nursing facility for purposes of subchapter XVIII of this chapter.

(9) Sharing of information

Notwithstanding any other provision of law, all information concerning nursing facilities required by this section to be filed with the Secretary or a State agency shall be made available by such facilities to Federal or State employees for purposes consistent with the effective administration of programs established under this subchapter and subchapter XVIII of this chapter, including investigations by State medicaid fraud control units.

3. 42 C.F.R. 488.301 provides as follows:

§ 488.301 Definitions

As used in this subpart—

Abbreviated standard survey means a survey other than a standard survey that gathers information primarily through resident-centered techniques on facility compliance with the requirements for participation. An abbreviated standard survey may be premised on complaints received; a change of ownership, management, or director of nursing; or other indicators of specific concern.

Abuse means the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish.

Deficiency means a SNF's or NF's failure to meet a participation requirement specified in the Act or in part 483, subpart B of this chapter.

Dually participating facility means a facility that has a provider agreement in both the Medicare and Medicaid programs.

Extended survey means a survey that evaluates additional participation requirements subsequent to finding substandard quality of care during a standard survey.

Facility means a SNF or NF, or a distinct part SNF or NF, in accordance with § 483.5 of this chapter.

Immediate family means husband or wife; natural or adoptive parent, child or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law,

son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild.

Immediate jeopardy means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.

Misappropriation of resident property means the deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a resident's belongings or money without the resident's consent.

Neglect means failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness.

Noncompliance means any deficiency that causes a facility to not be in substantial compliance.

Nurse aide means an individual, as defined in § 483.75(e)(1) of this chapter.

Nursing facility (NF) means a Medicaid nursing facility.

Partial extended survey means a survey that evaluates additional participation requirements subsequent to finding substandard quality of care during an abbreviated standard survey.

Skilled nursing facility (SNF) means a Medicare nursing facility.

Standard survey means a periodic, resident-centered inspection which gathers information about the quality

of service furnished in a facility to determine compliance with the requirements for participation.

Substandard quality of care means one or more deficiencies related to participation requirements under § 483.13, Resident behavior and facility practices, § 483.15, Quality of life, or § 483.25, Quality of care of this chapter, which constitute either immediate jeopardy to resident health or safety; a pattern of or widespread actual harm that is not immediate jeopardy; or a widespread potential for more than minimal harm, but less than immediate jeopardy, with no actual harm.

Substantial compliance means a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm.

Validation survey means a survey conducted by the Secretary within 2 months following a standard survey, abbreviated standard survey, partial extended survey, or extended survey for the purpose of monitoring State survey agency performance.

4. 42 C.F.R. 488.400-488.456 provides as follows:

Subpart F—Enforcement of Compliance for Long-Term Care Facilities with Deficiencies

SOURCE: 59 FR 56243, Nov. 10, 1994, unless otherwise noted.

§ 488.400 Statutory basis.

Sections 1819(h) and 1919(h) of the Act specify remedies that may be used by the Secretary or the State respectively when a SNF or a NF is not in substantial compliance with the requirements for participation in the Medicare and Medicaid programs. These sections also provide for ensuring prompt compliance and specify that these remedies are in addition to any others available under State or Federal law, and, except for civil money penalties, are imposed prior to the conduct of a hearing.

§ 488.401 Definitions.

As used in this subpart—

New admission means a resident who is admitted to the facility on or after the effective date of a denial of payment remedy and, if previously admitted, has been discharged before that effective date. Residents admitted before the effective date of the denial of payment, and taking temporary leave, are not considered new admissions, nor subject to the denial of payment.

Plan of correction means a plan developed by the facility and approved by HCFA or the survey agency that describes the actions the facility will take to correct deficiencies and specifies the date by which those deficiencies will be corrected.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.402 General provisions.

(a) *Purpose of remedies.* The purpose of remedies is to ensure prompt compliance with program requirements.

(b) *Basis for imposition and duration of remedies.* When HCFA or the State chooses to apply one or more remedies specified in § 488.406, the remedies are applied on the basis of noncompliance found during surveys conducted by HCFA or by the survey agency.

(c) *Number of remedies.* HCFA or the State may apply one or more remedies for each deficiency constituting noncompliance or for all deficiencies constituting noncompliance.

(d) *Plan of correction requirement.* (1) Except as specified in paragraph (d)(2) of this section, regardless of which remedy is applied, each facility that has deficiencies with respect to program requirements must submit a plan of correction for approval by HCFA or the survey agency.

(2) *Isolated deficiencies.* A facility is not required to submit a plan of correction when it has deficiencies that are isolated and have a potential for minimal harm, but no actual harm has occurred.

(e) *Disagreement regarding remedies.* If the State and HCFA disagree on the decision to impose a remedy, the disagreement is resolved in accordance with § 488.452.

(f) *Notification requirements*—(1) Except when the State is taking action against a non-State operated NF, HCFA or the State (as authorized by HCFA) gives the provider notice of the remedy, including the—

(i) Nature of the noncompliance;

(ii) Which remedy is imposed;

(iii) Effective date of the remedy; and

(iv) Right to appeal the determination leading to the remedy.

(2) When a State is taking action against a non-State operated NF, the State's notice must include the same information required by HCFA in paragraph (f)(1) of this section.

(3) *Immediate jeopardy—2 day notice.* Except for civil money penalties and State monitoring imposed when there is immediate jeopardy, for all remedies specified in § 488.406 imposed when there is immediate jeopardy, the notice must be given at least 2 calendar days before the effective date of the enforcement action.

(4) *No immediate jeopardy—15 day notice.* Except for civil money penalties and State monitoring, notice must be given at least 15 calendar days before the effective date of the enforcement action in situations in which there is no immediate jeopardy.

(5) *Latest date of enforcement action.* The 2 and 15-day notice periods begin when the facility receives the notice, but, in no event will the effective date of the

enforcement action be later than 20 calendar days after the notice is sent.

(6) *Civil money penalties.* For civil money penalties, the notices must be given in accordance with the provisions of §§ 488.434 and 488.440.

(7) *State monitoring.* For State monitoring, no prior notice is required.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.404 Factors to be considered in selecting remedies.

(a) *Initial assessment.* In order to select the appropriate remedy, if any, to apply to a facility with deficiencies, HCFA and the State determine the seriousness of the deficiencies.

(b) *Determining seriousness of deficiencies.* To determine the seriousness of the deficiency, HCFA considers and the State must consider at least the following factors:

(1) Whether a facility's deficiencies constitute—

(i) No actual harm with a potential for minimal harm;

(ii) No actual harm with a potential for more than minimal harm, but not immediate jeopardy;

(iii) Actual harm that is not immediate jeopardy; or

(iv) Immediate jeopardy to resident health or safety.

(2) Whether the deficiencies—

(i) Are isolated;

(ii) Constitute a pattern; or

(iii) Are widespread.

(c) *Other factors which may be considered in choosing a remedy within a remedy category.* Following the initial assessment, HCFA and the State may consider other factors, which may include, but are not limited to the following:

(1) The relationship of the one deficiency to other deficiencies resulting in noncompliance.

(2) The facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

§ 488.406 Available remedies.

(a) *General.* In addition to the remedy of termination of the provider agreement, the following remedies are available:

(1) Temporary management.

(2) Denial of payment including—

(i) Denial of payment for all individuals, imposed by HCFA, to a—

(A) Skilled nursing facility, for Medicare;

(B) State, for Medicaid; or

(ii) Denial of payment for all new admissions.

(3) Civil money penalties.

(4) State monitoring.

(5) Transfer of residents.

(6) Closure of the facility and transfer of residents.

(7) Directed plan of correction.

(8) Directed in-service training.

(9) Alternative or additional State remedies approved by HCFA.

(b) *Remedies that must be established.* At a minimum, and in addition to termination of the provider agreement, the State must establish the following remedies or approved alternatives to the following remedies:

(1) Temporary management.

(2) Denial of payment for new admissions.

(3) Civil money penalties.

(4) Transfer of residents.

(5) Closure of the facility and transfer of residents.

(6) State monitoring.

(c) *State plan requirement.* If a State wishes to use remedies for noncompliance that are either additional or alternative to those specified in paragraphs (a) or (b) of this section, it must—

(1) Specify those remedies in the State plan; and

(2) Demonstrate to HCFA's satisfaction that those remedies are as effective as the remedies listed in paragraph (a) of this section, for deterring noncompliance and correcting deficiencies.

(d) *State remedies in dually participating facilities.* If the State's remedy is unique to the State plan and has been approved by HCFA, then that remedy, as imposed by the State under its Medicaid authority, may be imposed by HCFA against the Medicare provider agreement of a dually participating facility.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.408 Selection of remedies.

(a) *Categories of remedies.* In this section, the remedies specified in § 488.406(a) are grouped into categories and applied to deficiencies according to how serious the noncompliance is.

(b) *Application of remedies.* After considering the factors specified in § 488.404, as applicable, if HCFA and the State choose to impose remedies, as provided in paragraphs (c)(1), (d)(1) and (e)(1) of this section, for facility noncompliance, instead of, or in addition to, termination of the provider agreement, HCFA does and the State must follow the criteria set forth in paragraphs (c)(2), (d)(2), and (e)(2) of this section, as applicable.

(c) *Category 1.* (1) Category 1 remedies include the following:

(i) Directed plan of correction.

(ii) State monitoring.

(iii) Directed in-service training.

(2) HCFA does or the State must apply one or more of the remedies in Category 1 when there—

(i) Are isolated deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or

(ii) Is a pattern of deficiencies that constitutes no actual harm with a potential for more than minimal harm but not immediate jeopardy.

(3) Except when the facility is in substantial compliance, HCFA or the State may apply one or more of the remedies in Category 1 to any deficiency.

(d) *Category 2.* (1) Category 2 remedies include the following:

(i) Denial of payment for new admissions.

(ii) Denial of payment for all individuals imposed only by HCFA.

(iii) Civil money penalties of $50-3,000 per day.

(2) HCFA applies one or more of the remedies in Category 2, or, except for denial of payment for all individuals, the State must apply one or more of the remedies in Category 2 when there are—

(i) Widespread deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or

(ii) One or more deficiencies that constitute actual harm that is not immediate jeopardy.

(3) HCFA or the State may apply one or more of the remedies in Category 2 to any deficiency except when—

(i) The facility is in substantial compliance; or

(ii) HCFA or the State imposes a civil money penalty for a deficiency that constitutes immediate jeopardy, the penalty must be in the upper range of penalty amounts, as specified in § 488.438(a).

(e) *Category 3.* (1) Category 3 remedies include the following:

(i) Temporary management.

(ii) Immediate termination.

(iii) Civil money penalties of $3,050-$10,000 per day.

(2) When there are one or more deficiencies that constitute immediate jeopardy to resident health or safety—

(i) HCFA does and the State must do one or both of the following:

(A) Impose temporary management; or

(B) Terminate the provider agreement;

(ii) HCFA and the State may impose a civil money penalty of $3,050-$10,000 per day, in addition to imposing the remedies specified in paragraph (e)(2)(i) of this section.

(3) When there are widespread deficiencies that constitute actual harm that is not immediate jeopardy, HCFA and the State may impose temporary management, in addition to Category 2 remedies.

(f) *Plan of correction.* (1) Except as specified in paragraph (f)(2) of this section, each facility that has a deficiency with regard to a requirement for long term care facilities must submit a plan of correction for approval by HCFA or the State, regardless of—

(i) Which remedies are imposed; or

(ii) The seriousness of the deficiencies.

(2) When there are only isolated deficiencies that HCFA or the State determines constitute no actual harm with a potential for minimal harm, the facility need not submit a plan of correction.

(g) *Appeal of a certification of noncompliance.* (1) A facility may appeal a certification of noncompliance leading to an enforcement remedy.

(2) A facility may not appeal the choice of remedy, including the factors considered by HCFA or the State in selecting the remedy, specified in § 488.404.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.410 Action when there is immediate jeopardy.

(a) If there is immediate jeopardy to resident health or safety, the State must (and HCFA does) either terminate the provider agreement within 23 calendar days of the last date of the survey or appoint a temporary manager to remove the immediate jeopardy.

The rules for appointment of a temporary manager in an immediate jeopardy situation are as follows:

(1) HCFA does and the State must notify the facility that a temporary manager is being appointed.

(2) If the facility fails to relinquish control to the temporary manager, HCFA does and the State must terminate the provider agreement within 23 calendar days of the last day of the survey, if the immediate jeopardy is not removed. In these cases, State monitoring may be imposed pending termination.

(3) If the facility relinquishes control to the temporary manager, the State must (and HCFA does) notify the facility that, unless it removes the immediate jeopardy, its provider agreement will be terminated within 23 calendar days of the last day of the survey.

(4) HCFA does and the State must terminate the provider agreement within 23 calendar days of the last day of survey if the immediate jeopardy has not been removed.

(b) HCFA or the State may also impose other remedies, as appropriate.

(c)(1) In a NF or dually participating facility, if either HCFA or the State finds that a facility's noncompliance poses immediate jeopardy to resident health or safety, HCFA or the State must notify the other of such a finding.

(2) HCFA will or the State must do one or both of the following:

(i) Take immediate action to remove the jeopardy and correct the noncompliance through temporary management.

(ii) Terminate the facility's participation under the State plan. If this is done, HCFA will also terminate the facility's participation in Medicare if it is a dually participating facility.

(d) The State must provide for the safe and orderly transfer of residents when the facility is terminated.

(e) If the immediate jeopardy is also substandard quality of care, the State survey agency must notify attending physicians and the State board responsible for licensing the facility administrator of the finding of substandard quality of care, as specified in § 488.325(h).

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.412 Action when there is no immediate jeopardy.

(a) If a facility's deficiencies do not pose immediate jeopardy to residents' health or safety, and the facility is not in substantial compliance, HCFA or the State may terminate the facility's provider agreement or may allow the facility to continue to participate for no longer than 6 months from the last day of the survey if—

(1) The State survey agency finds that it is more appropriate to impose alternative remedies than to terminate the facility's provider agreement;

(2) The State has submitted a plan and timetable for corrective action approved by HCFA; and

(3) The facility in the case of a Medicare SNF or the State in the case of a Medicaid NF agrees to repay to the Federal government payments received after the last day of the survey that first identified the deficiencies if corrective action is not taken in accordance with the approved plan of correction.

(b) If a facility does not meet the criteria for continuation of payment under paragraph (a) of this section, HCFA will and the State must terminate the facility's provider agreement.

(c) HCFA does and the State must deny payment for new admissions when a facility is not in substantial compliance 3 months after the last day of the survey.

(d) HCFA terminates the provider agreement for SNFs and NFs, and stops FFP to a State for a NF for which participation was continued under paragraph (a) of this section, if the facility is not in substantial compliance within 6 months of the last day of the survey.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.414 Action when there is repeated substandard quality of care.

(a) *General.* If a facility has been found to have provided substandard quality of care on the last three consecutive standard surveys, as defined in § 488.305, regardless of other remedies provided—

(1) HCFA imposes denial of payment for all new admissions, as specified in § 488.417, or denial of all payments, as specified in § 488.418;

(2) The State must impose denial of payment for all new admissions, as specified in § 488.417; and

(3) HCFA does and the State survey agency must impose State monitoring, as specified in § 488.422, until the facility has demonstrated to the satisfaction of HCFA or the State, that it is in substantial compliance with all requirements and will remain in substantial compliance with all requirements.

(b) *Repeated noncompliance.* For purposes of this section, repeated noncompliance is based on the repeated finding of substandard quality of care and not on the basis that the substance of the deficiency or the exact tag number for the deficiency was repeated.

(c) *Standard surveys to which this provision applies.* Standard surveys completed by the State survey agency on or after October 1, 1990, are used to determine whether the threshold of three consecutive standard surveys is met.

(d) *Program participation.* (1) The determination that a certified facility has repeated instances of substandard quality of care is made without regard to any variances in the facility's program participation (that is, any standard survey completed for Medicare, Medicaid or both programs will be considered).

(2) Termination would allow the count of repeated substandard quality of care surveys to start over.

(3) Change of ownership. (i) A facility may not avoid a remedy on the basis that it underwent a change of ownership.

(ii) In a facility that has undergone a change of ownership, HCFA does not and the State may not restart the count of repeated substandard quality of care surveys unless the new owner can demonstrate to the satisfaction of HCFA or the State that the poor past performance no longer is a factor due to the change in ownership.

(e) *Facility alleges corrections or achieves compliance after repeated substandard quality of care is identified.* (1) If a penalty is imposed for repeated substandard quality of care, it will continue until the facility has demonstrated to the satisfaction of HCFA or the State that it is in substantial compliance with the requirements and that it will remain in substantial compliance with the requirements for a period of time specified by HCFA or the State.

(2) A facility will not avoid the imposition of remedies or the obligation to demonstrate that it will remain in compliance when it—

(i) Alleges correction of the deficiencies cited in the most recent standard survey; or

(ii) Achieves compliance before the effective date of the remedies.

§ 488.415 Temporary management.

(a) *Definition.* Temporary management means the temporary appointment by HCFA or the State of a substitute facility manager or administrator with authority to hire, terminate or reassign staff, obligate facility funds, alter facility procedures, and manage the

facility to correct deficiencies identified in the facility's operation.

(b) *Qualifications.* The temporary manager must—

(1) Be qualified to oversee correction of deficiencies on the basis of experience and education, as determined by the State;

(2) Not have been found guilty of misconduct by any licensing board or professional society in any State;

(3) Have, or a member of his or her immediate family have, no financial ownership interest in the facility; and

(4) Not currently serve or, within the past 2 years, have served as a member of the staff of the facility.

(c) *Payment of salary.* The temporary manager's salary—

(1) Is paid directly by the facility while the temporary manager is assigned to that facility; and

(2) Must be at least equivalent to the sum of the following—

(i) The prevailing salary paid by providers for positions of this type in what the State considers to be the facility's geographic area;

(ii) Additional costs that would have reasonably been incurred by the provider if such person had been in an employment relationship; and

(iii) Any other costs incurred by such a person in furnishing services under such an arrangement or as otherwise set by the State.

(3) May exceed the amount specified in paragraph (c)(2) of this section if the State is otherwise unable to attract a qualified temporary manager.

(d) *Failure to relinquish authority to temporary management*—(1) *Termination of provider agreement.* If a facility fails to relinquish authority to the temporary manager as described in this section, HCFA will or the State must terminate the provider agreement in accordance with § 488.456.

(2) *Failure to pay salary of temporary manager.* A facility's failure to pay the salary of the temporary manager is considered a failure to relinquish authority to temporary management.

(e) *Duration of temporary management.* Temporary management ends when the facility meets any of the conditions specified in § 488.454(c).

§ 488.417 Denial of payment for all new admissions.

(a) *Optional denial of payment.* Except as specified in paragraph (b) of this section, HCFA or the State may deny payment for all new admissions when a facility is not in substantial compliance with the requirements, as defined in § 488.401, as follows:

(1) *Medicare facilities.* In the case of Medicare facilities, HCFA may deny payment to the facility.

(2) *Medicaid facilities.* In the case of Medicaid facilities—

(i) The State may deny payment to the facility; and

(ii) HCFA may deny payment to the State for all new Medicaid admissions to the facility.

(b) *Required denial of payment.* HCFA does or the State must deny payment for all new admissions when—

(1) The facility is not in substantial compliance, as defined in § 488.401, 3 months after the last day of the survey identifying the noncompliance; or

(2) The State survey agency has cited a facility with substandard quality of care on the last three consecutive standard surveys.

(c) *Resumption of payments: Repeated instances of substandard quality of care.* When a facility has repeated instances of substandard quality of care, payments to the facility or, under Medicaid, HCFA payments to the State on behalf of the facility, resume on the date that—

(1) The facility achieves substantial compliance as indicated by a revisit or written credible evidence acceptable to HCFA (for all facilities except non-State operated NFs against which HCFA is imposing no remedies) or the State (for non-State operated NFs against which HCFA is imposing no remedies); and

(2) HCFA (for all facilities except non-State operated NFs against which HCFA is imposing no remedies) or the State (for non-State operated NFs against which HCFA is imposing no remedies) believes

that the facility is capable of remaining in substantial compliance.

(d) *Resumption of payments: No repeated instances of substandard quality of care.* When a facility does not have repeated instances of substandard quality of care, payments to the facility or, under Medicaid, HCFA payments to the State on behalf of the facility, resume prospectively on the date that the facility achieves substantial compliance, as indicated by a revisit or written credible evidence acceptable to HCFA (under Medicare) or the State (under Medicaid).

(e) *Restriction.* No payments to a facility or, under Medicaid, HCFA payments to the State on behalf of the facility, are made for the period between the date that the—

(1) Denial of payment remedy is imposed; and

(2) Facility achieves substantial compliance, as determined by HCFA or the State.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.418 Secretarial authority to deny all payments.

(a) *HCFA option to deny all payment.* If a facility has not met a requirement, in addition to the authority to deny payment for all new admissions as specified in § 488.417, HCFA may deny any further payment for all Medicare residents in the facility and to the State for all Medicaid residents in the facility.

(b) *Prospective resumption of payment.* Except as provided in paragraphs (d) and (e) of this section, if the facility achieves substantial compliance, HCFA re-

sumes payment prospectively from the date that it verifies as the date that the facility achieved substantial compliance.

(c) *Restriction on payment after denial of payment is imposed.* If payment to the facility or to the State resumes after denial of payment for all residents, no payment is made for the period between the date that—

(1) Denial of payment was imposed; and

(2) HCFA verifies as the date that the facility achieved substantial compliance.

(d) *Retroactive resumption of payment.* Except when a facility has repeated instances of substandard quality of care, as specified in paragraph (e) of this section, when HCFA or the State finds that the facility was in substantial compliance before the date of the revisit, or before HCFA or the survey agency received credible evidence of such compliance, payment is resumed on the date that substantial compliance was achieved, as determined by HCFA.

(e) *Resumption of payment—repeated instances of substandard care.* When HCFA denies payment for all Medicare residents for repeated instances of substandard quality of care, payment is resumed when—

(1) The facility achieved substantial compliance, as indicated by a revisit or written credible evidence acceptable to HCFA; and

(2) HCFA believes that the facility will remain in substantial compliance.

§ 488.422 State monitoring.

(a) A State monitor—

(1) Oversees the correction of deficiencies specified by HCFA or the State survey agency at the facility site and protects the facility's residents from harm;

(2) Is an employee or a contractor of the survey agency;

(3) Is identified by the State as an appropriate professional to monitor cited deficiencies;

(4) Is not an employee of the facility;

(5) Does not function as a consultant to the facility; and

(6) Does not have an immediate family member who is a resident of the facility to be monitored.

(b) A State monitor must be used when a survey agency has cited a facility with substandard quality of care deficiencies on the last 3 consecutive standard surveys.

(c) State monitoring is discontinued when—

(1) The facility has demonstrated that it is in substantial compliance with the requirements, and, if imposed for repeated instances of substandard quality of care, will remain in compliance for a period of time specified by HCFA or the State; or

(2) Termination procedures are completed.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.424 Directed plan of correction.

HCFA, the State survey agency, or the temporary manager (with HCFA or State approval) may develop a plan of correction and HCFA, the State, or the temporary manager require a facility to take action within specified time-frames.

§ 488.425 Directed inservice training.

(a) *Required training.* HCFA or the State agency may require the staff of a facility to attend an inservice training program if—

(1) The facility has a pattern of deficiencies that indicate noncompliance; and

(2) Education is likely to correct the deficiencies.

(b) *Action following training.* After the staff has received inservice training, if the facility has not achieved substantial compliance, HCFA or the State may impose one or more other remedies specified in § 488.406.

(c) *Payment.* The facility pays for directed inservice training.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.426 Transfer of residents, or closure of the facility and transfer of residents.

(a) *Transfer of residents, or closure of the facility and transfer of residents in an emergency.* In an emergency, the State has the authority to—

(1) Transfer Medicaid and Medicare residents to another facility; or

(2) Close the facility and transfer the Medicaid and Medicare residents to another facility.

(b) *Required transfer when a facility's provider agreement is terminated.* When the State or HCFA terminates a facility's provider agreement, the State arranges for the safe and orderly transfer of all Medicare and Medicaid residents to another facility.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.430 Civil money penalties: Basis for imposing penalty.

(a) HCFA or the State may impose a civil money penalty for the number of days a facility is not in substantial compliance with one or more participation requirements, regardless of whether or not the deficiencies constitute immediate jeopardy.

(b) HCFA or the State may impose a civil money penalty for the number of days of past noncompliance since the last standard survey, including the number of days of immediate jeopardy.

§ 488.432 Civil money penalties: When penalty is collected.

(a) *When facility requests a hearing.* (1) A facility must request a hearing on the determination of the noncompliance that is the basis for imposition of the civil money penalty within the time specified in one of the following sections:

(i) Section 498.40 of this chapter for a

(A) SNF;

(B) Dually participating facility;

(C) State-operated NF; or

(D) Non-State operated NF against which HCFA is imposing remedies.

(ii) Section 431.153 of this chapter for a non-State operated NF that is not subject to imposition of remedies by HCFA.

(2) If a facility requests a hearing within the time specified in paragraph (a)(1) of this section, HCFA or the State initiates collection of the penalty when there is a final administrative decision that upholds HCFA's or the State's determination of noncompliance after the facility achieves substantial compliance or is terminated.

(b) *When facility does not request a hearing.* If a facility does not request a hearing, in accordance with paragraph (a) of this section, HCFA or the State initiates collection of the penalty when the facility—

(1) Achieves substantial compliance; or

(2) Is terminated.

(c) *When facility waives a hearing.* If a facility waives its right to a hearing in writing, as specified in § 488.436, HCFA or the State initiates collection of the penalty when the facility—

(1) Achieves substantial compliance; or

(2) Is terminated.

(d) Accrual and computation of penalties for a facility that—

(1) Requests a hearing or does not request a hearing are specified in § 488.440;

(2) Waives its right to a hearing in writing, are specified in §§ 488.436(b) and 488.440.

(e) The collection of civil money penalties is made as provided in § 488.442.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.434 Civil money penalties: Notice of penalty.

(a) *HCFA notice of penalty.* (1) HCFA sends a written notice of the penalty to the facility for all facilities except non-State operated NFs when the State is imposing the penalty.

(2) *Content of notice.* The notice that HCFA sends includes—

(i) The nature of the noncompliance;

(ii) The statutory basis for the penalty;

(iii) The amount of penalty per day of noncompliance;

(iv) Any factors specified in § 488.438(f) that were considered when determining the amount of the penalty;

(v) The date on which the penalty begins to accrue;

(vi) When the penalty stops accruing;

(vii) When the penalty is collected; and

(viii) Instructions for responding to the notice, including a statement of the facility's right to a hearing, and the implication of waiving a hearing, as provided in § 488.436.

(b) *State notice of penalty.* (1) The State must notify the facility in accordance with State procedures for all non-State operated NFs when the State takes the action.

(2) The State's notice must—

(i) Be in writing; and

(ii) Include, at a minimum, the information specified in paragraph (a)(2) of this section.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.436 Civil money penalties: Waiver of hearing, reduction of penalty amount.

(a) *Waiver of a hearing.* The facility may waive the right to a hearing, in writing, within 60 days from the date of the notice imposing the civil money penalty.

(b) *Reduction of penalty amount.* (1) If the facility waives its right to a hearing in accordance with the procedures specified in paragraph (a) of this section, HCFA or the State reduces the civil money penalty amount by 35 percent.

(2) If the facility does not waive its right to a hearing in accordance with the procedures specified in paragraph (a) of this section, the civil money penalty is not reduced by 35 percent.

[59 FR 56243, Nov. 10, 1994; 62 FR 44221, Aug. 20, 1997]

§ 488.438 Civil money penalties: Amount of penalty.

(a) *Amount of penalty.* The penalties are within the following ranges, set at $50 increments:

(1) *Upper range—$3,050-$10,000.* Penalties in the range of $3,050-$10,000 per day are imposed for deficiencies constituting immediate jeopardy, and as specified in paragraph (d)(2) of this section.

(2) *Lower range—$50-$3,000.* Penalties in the range of $50-$3,000 per day are imposed for deficiencies that do not constitute immediate jeopardy, but either caused actual harm, or caused no actual harm, but have the potential for more than minimal harm.

(b) *Basis for penalty amount.* The amount of penalty is based on HCFA's or the State's assessment of factors listed in paragraph (f) of this section.

(c) *Decreased penalty amounts.* Except as specified in paragraph (d)(2) of this section, if immediate jeopardy is removed, but the noncompliance continues, HCFA or the State will shift the penalty amount to the lower range.

(d) *Increased penalty amounts.* (1) Before the hearing, HCFA or the State may propose to increase the penalty amount for facility noncompliance which, after imposition of a lower level penalty amount,

becomes sufficiently serious to pose immediate jeopardy.

(2) HCFA does and the State must increase the penalty amount for any repeated deficiencies for which a lower level penalty amount was previously imposed, regardless of whether the increased penalty amount would exceed the range otherwise reserved for non-immediate jeopardy deficiencies.

(3) Repeated deficiencies are deficiencies in the same regulatory grouping of requirements found at the last survey, subsequently corrected, and found again at the next survey.

(e) *Review of the penalty.* When an administrative law judge or State hearing officer (or higher administrative review authority) finds that the basis for imposing a civil money penalty exists, as specified in § 488.430, the administrative law judge or State hearing officer (or higher administrative review authority) may not—

(1) Set a penalty of zero or reduce a penalty to zero;

(2) Review the exercise of discretion by HCFA or the State to impose a civil money penalty; and

(3) Consider any factors in reviewing the amount of the penalty other than those specified in paragraph (f) of this section.

(f) *Factors affecting the amount of penalty.* In determining the amount of penalty, HCFA does or the State must take into account the following factors:

(1) The facility's history of noncompliance, including repeated deficiencies.

(2) The facility's financial condition.

(3) The factors specified in § 488.404.

(4) *The facility's degree of culpability. Culpability* for purposes of this paragraph includes, but is not limited to, neglect, indifference, or disregard for resident care, comfort or safety. The absence of culpability is not a mitigating circumstance in reducing the amount of the penalty.

§ 488.440 Civil money penalties: Effective date and duration of penalty.

(a) *When penalty begins to accrue.* The civil money penalty may start accruing as early as the date that the facility was first out of compliance, as determined by HCFA or the State.

(b) *Duration of penalty.* The civil money penalty is computed and collectible, as specified in §§ 488.432 and 488.442, for the number of days of noncompliance until the date the facility achieves substantial compliance, or, if applicable, the date of termination when—

(1) HCFA's or the State's decision of noncompliance is upheld after a final administrative decision;

(2) The facility waives its right to a hearing in accordance with § 488.436; or

(3) The time for requesting a hearing has expired and HCFA or the State has not received a hearing request from the facility.

(c) The entire accrued penalty is due and collectible, as specified in the notice sent to the provider under paragraphs (d) and (e) of this section.

(d) When a facility achieves substantial compliance, HCFA does or the State must send a separate notice to the facility containing—

(1) The amount of penalty per day;

(2) The number of days involved;

(3) The total amount due;

(4) The due date of the penalty; and

(5) The rate of interest assessed on the unpaid balance beginning on the due date, as provided in § 488.442.

(e) In the case of a terminated facility, HCFA does or the State must send this penalty information after the—

(1) Final administrative decision is made;

(2) Facility has waived its right to a hearing in accordance with § 488.436; or

(3) Time for requesting a hearing has expired and HCFA or the state has not received a hearing request from the facility.

(f) *Accrual of penalties when there is no immediate jeopardy.* (1) In the case of noncompliance that does not pose immediate jeopardy, the daily accrual of civil money penalties is imposed for the days of noncompliance prior to the notice specified in § 488.434 and

an additional period of no longer than 6 months following the last day of the survey.

(2) After the period specified in paragraph (f)(1) of this section, if the facility has not achieved substantial compliance, HCFA terminates the provider agreement and the State may terminate the provider agreement.

(g) *Accrual of penalties when there is immediate jeopardy.* (1) When a facility has deficiencies that pose immediate jeopardy, HCFA does or the State must terminate the provider agreement within 23 calendar days after the last day of the survey if the immediate jeopardy remains.

(2) The accrual of the civil money penalty stops on the day the provider agreement is terminated.

(h) *Documenting substantial compliance.* (1) If an on-site revisit is necessary to confirm substantial compliance and the provider can supply documentation acceptable to HCFA or the State agency that substantial compliance was achieved on a date preceding the revisit, penalties only accrue until that date of correction for which there is written credible evidence.

(2) If an on-site revisit is not necessary to confirm substantial compliance, penalties only accrue until the date of correction for which HCFA or the State receives and accepts written credible evidence.

§ 488.442 Civil money penalties: Due date for payment of penalty.

(a) *When payments are due*—(1) *After a final administrative decision.* A civil money penalty payment is due 15 days after a final administrative decision is made when—

(i) The facility achieves substantial compliance before the final administrative decision; or

(ii) The effective date of termination occurs before the final administrative decision.

(2) *When no hearing was requested.* A civil money penalty payment is due 15 days after the time period for requesting a hearing has expired and a hearing request was not received when—

(i) The facility achieved substantial compliance before the hearing request was due; or

(ii) The effective date of termination occurs before the hearing request was due.

(3) *After a request to waive a hearing.* A civil money penalty payment is due 15 days after receipt of the written request to waive a hearing when—

(i) The facility achieved substantial compliance before HCFA or the State received the written waiver of hearing; or

(ii) The effective date of termination occurs before HCFA or the State received the written waiver of hearing.

(4) *After substantial compliance is achieved.* A civil money penalty payment is due 15 days after substantial compliance is achieved when—

(i) The final administrative decision is made before the facility came into substantial compliance;

(ii) The facility did not file a timely hearing request before it came into substantial compliance; or

(iii) The facility waived its right to a hearing before it came into substantial compliance;

(5) *After the effective date of termination.* A civil money penalty payment is due 15 days after the effective date of termination, if before the effective date of termination—

(i) The final administrative decision was made;

(ii) The time for requesting a hearing has expired and the facility did not request a hearing; or

(iii) The facility waived its right to a hearing.

(6) In the cases specified in paragraph (a)(4) of this section, the period of noncompliance may not extend beyond 6 months from the last day of the survey.

(b) *Deduction of penalty from amount owed.* The amount of the penalty, when determined, may be deducted from any sum then or later owing by HCFA or the State to the facility.

(c) *Interest*—(1) *Assessment.* Interest is assessed on the unpaid balance of the penalty, beginning on the due date.

(2) *Medicare interest.* Medicare rate of interest is the higher of—

(i) The rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date of the notice of the penalty amount due (published quarterly in the Federal Register by HHS under 45 CFR 30.13(a)); or

(ii) The current value of funds (published annually in the Federal Register by the Secretary of the Treasury, subject to quarterly revisions).

(3) *Medicaid interest.* The interest rate for Medicaid is determined by the State.

(d) *Penalties collected by HCFA.* Civil money penalties and corresponding interest collected by HCFA from—

(1) Medicare-participating facilities are deposited as miscellaneous receipts of the United States Treasury; and

(2) Medicaid-participating facilities are returned to the State.

(e) *Collection from dually participating facilities.* Civil money penalties collected from dually participating facilities are deposited as miscellaneous receipts of the United States Treasury and returned to the State in proportion commensurate with the relative proportions of Medicare and Medicaid beds at the facility actually in use by residents covered by the respective programs on the date the civil money penalty begins to accrue.

(f) *Penalties collected by the State.* Civil money penalties collected by the State must be applied to the protection of the health or property of residents of facilities that the State or HCFA finds noncompliant, such as—

(1) Payment for the cost of relocating residents to other facilities;

(2) State costs related to the operation of a facility pending correction of deficiencies or closure; and

(3) Reimbursement of residents for personal funds or property lost at a facility as a result of actions by the facility or by individuals used by the facility to provide services to residents.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.444 Civil money penalties: Settlement of penalties.

(a) HCFA has authority to settle cases at any time prior to a final administrative decision for Medicare-only SNFs, State-operated facilities, or other facilities for which HCFA's enforcement action prevails, in accordance with § 488.330.

(b) The State has the authority to settle cases at any time prior to the evidentiary hearing decision for all cases in which the State's enforcement action prevails.

§ 488.450 Continuation of payments to a facility with deficiencies.

(a) *Criteria.* (1) HCFA may continue payments to a facility not in substantial compliance for the periods specified in paragraph (c) of this section if the following criteria are met:

(i) The State survey agency finds that it is more appropriate to impose alternative remedies than to terminate the facility;

(ii) The State has submitted a plan and timetable for corrective action approved by HCFA; and

(iii) The facility, in the case of a Medicare SNF, or the State, in the case of a Medicaid NF, agrees to repay the Federal government payments received under this provision if corrective action is not taken in accordance with the approved plan and timetable for corrective action.

(2) HCFA or the State may terminate the SNF or NF agreement before the end of the correction period if the criteria in paragraph (a)(1) of this section are not met.

(b) *Cessation of payments.* If termination is not sought, either by itself or along with another remedy or remedies, or any of the criteria set forth in paragraph (a)(1) of this section are not met or agreed to by either the facility or the State, the facility or State will receive no Medicare or Federal Medicaid payments, as applicable, from the last day of the survey.

(c) *Period of continued payments.* If the conditions in paragraph (a)(1) of this section are met, HCFA may continue payments to a Medicare facility or to the State for a Medicaid facility with noncompliance that does not constitute immediate jeopardy for up to 6 months from the last day of the survey.

(d) *Failure to achieve substantial compliance.* If the facility does not achieve substantial compliance by the end of the period specified in paragraph (c) of this section,

(1) HCFA will—

(i) Terminate the provider agreement of the Medicare SNF in accordance with § 488.456; or

(ii) Discontinue Federal funding to the SNF for Medicare; and

(iii) Discontinue FFP to the State for the Medicaid NF.

(2) The State may terminate the provider agreement for the NF.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.452 State and Federal disagreements involving findings not in agreement in non-State operated NFs and dually participating facilities when there is no immediate jeopardy.

The following rules apply when HCFA and the State disagree over findings of noncompliance or application

of remedies in a non-State operated NF or dually participating facility:

(a) *Disagreement over whether facility has met requirements.* (1) The State's finding of noncompliance takes precedence when—

(i) HCFA finds that a NF or a dually participating facility is in substantial compliance with the participation requirements; and

(ii) The State finds that a NF or dually participating facility has not achieved substantial compliance.

(2) HCFA's findings of noncompliance take precedence when—

(i) HCFA finds that a NF or a dually participating facility has not achieved substantial compliance; and

(ii) The State finds that a NF or a dually participating facility is in substantial compliance with the participation requirements.

(3) When HCFA's survey findings take precedence, HCFA may—

(i) Impose any of the alternative remedies specified in § 488.406;

(ii) Terminate the provider agreement subject to the applicable conditions of § 488.450; and

(iii) Stop FFP to the State for a NF.

(b) *Disagreement over decision to terminate.* (1) HCFA's decision to terminate the participation of a facility takes precedence when—

(i) Both HCFA and the State find that the facility has not achieved substantial compliance; and

(ii) HCFA, but not the State, finds that the facility's participation should be terminated. HCFA will permit continuation of payment during the period prior to the effective date of termination not to exceed 6 months, if the applicable conditions of § 488.450 are met.

(2) The State's decision to terminate a facility's participation and the procedures for appealing such termination, as specified in § 431.153(c) of this chapter, takes precedence when—

(i) The State, but not HCFA, finds that a NF's participation should be terminated; and

(ii) The State's effective date for the termination of the NF's provider agreement is no later than 6 months after the last day of survey.

(c) *Disagreement over timing of termination of facility.* The State's timing of termination takes precedence if it does not occur later than 6 months after the last day of the survey when both HCFA and the State find that—

(1) A facility is not in substantial compliance; and

(2) The facility's participation should be terminated.

(d) *Disagreement over remedies.* (1) When HCFA or the State, but not both, establishes one or more remedies, in addition to or as an alternative to termination, the additional or alternative remedies will also apply when—

(i) Both HCFA and the State find that a facility has not achieved substantial compliance; and

(ii) Both HCFA and the State find that no immediate jeopardy exists.

(2) *Overlap of remedies.* When HCFA and the State establish one or more remedies, in addition to or as an alternative to termination, only the HCFA remedies apply when both HCFA and the State find that a facility has not achieved substantial compliance.

(e) Regardless of whether HCFA's or the State's decision controls, only one noncompliance and enforcement decision is applied to the Medicaid agreement, and for a dually participating facility, that same decision will apply to the Medicare agreement.

§ 488.454 Duration of remedies.

(a) Except as specified in paragraph (b) of this section, alternative remedies continue until—

(1) The facility has achieved substantial compliance, as determined by HCFA or the State based upon a revisit or after an examination of credible written evidence that it can verify without an on-site visit; or

(2) HCFA or the State terminates the provider agreement.

(b) In the cases of State monitoring and denial of payment imposed for repeated substandard quality of care, remedies continue until—

(1) HCFA or the State determines that the facility has achieved substantial compliance and is capable of remaining in substantial compliance; or

(2) HCFA or the State terminates the provider agreement.

(c) In the case of temporary management, the remedy continues until—

(1) HCFA or the State determines that the facility has achieved substantial compliance and is capable of remaining in substantial compliance;

(2) HCFA or the State terminates the provider agreement; or

(3) The facility which has not achieved substantial compliance reassumes management control. In this case, HCFA or the State initiates termination of the provider agreement and may impose additional remedies.

(d) If the facility can supply documentation acceptable to HCFA or the State survey agency that it was in substantial compliance, and was capable of remaining in substantial compliance, if necessary, on a date preceding that of the revisit, the remedies terminate on the date that HCFA or the State can verify as the date that substantial compliance was achieved and the facility demonstrated that it could maintain substantial compliance, if necessary.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.456 Termination of provider agreement.

(a) *Effect of termination.* Termination of the provider agreement ends—

(1) Payment to the facility; and

(2) Any alternative remedy.

(b) *Basis for termination.* (1) HCFA and the State may terminate a facility's provider agreement if a facility—

(i) Is not in substantial compliance with the requirements of participation, regardless of whether or not immediate jeopardy is present; or

(ii) Fails to submit an acceptable plan of correction within the time-frame specified by HCFA or the State.

(2) HCFA and the State terminate a facility's provider agreement if a facility—

(i) Fails to relinquish control to the temporary manager, if that remedy is imposed by HCFA or the State; or

(ii) Does not meet the eligibility criteria for continuation of payment as set forth in § 488.412(a)(1).

(c) *Notice of termination.* Before terminating a provider agreement, HCFA does and the State must notify the facility and the public—

(1) At least 2 calendar days before the effective date of termination for a facility with immediate jeopardy deficiencies; and

(2) At least 15 calendar days before the effective date of termination for a facility with non-immediate jeopardy deficiencies that constitute noncompliance.

(d) *Procedures for termination.* (1) HCFA terminates the provider agreement in accordance with procedures set forth in § 489.53 of this chapter; and

(2) The State must terminate the provider agreement of a NF in accordance with procedures specified in parts 431 and 442 of this chapter.

No. 98-1307

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In The

Supreme Court of the United States

OCTOBER TERM, 1998

DONNA E. SHALALA,
SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,
PETITIONERS,

v.

ILLINOIS COUNCIL ON LONG TERM CARE, INC.

On Petition For A Writ of Certiorari
To The United States Court of Appeals
For the Seventh Circuit

REPLY BRIEF FOR CROSS-PETITIONER

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REPLY BRIEF FOR CROSS-PETITIONER

I. The Vagueness of the "Grid" Is an Important and Far-Reaching Issue.

The Secretary admits that all nursing homes participating in Medicare and Medicaid are surveyed without prior notice about once a year. Br. in Opp. 3-4. The Secretary does not dispute that inspectors use the "grid" (*see* Cross-Pet. App. A-1) to determine enforcement remedies. It is undisputed that six out of the seven "scope and severity factors" on the grid are undefined. Surveyors have the discretion to plot a violation in virtually any box they wish, thereby instigating remedies on a subjective basis. The Secretary does not dispute that a facility cannot appeal the choice of remedy or the scope and severity designations. 42 C.F.R. § 488.408(g)(2). The Secretary fails to answer to the assertion that no body of administrative law is emerging that clarifies the meaning or application of the scope and

severity factors. Cross-Pet. 5. The nursing home industry is being subjected to a vague and arbitrary enforcement system that will not "correct itself" over time. The vagueness of the grid is thus an important issue.

The procedural question of the ripeness of the Council's claims should be equally important to this Court. The question of whether a facial constitutional challenge to regulations can be ripe even though unrelated to an individual claim is a close and significant issue. The Secretary does not dispute that this Court's analysis of the ripeness of the Council's claims will have broad precedential value for constitutional and statutory challenges under federal programs. *See* Cross-Pet. 6.

II. The Jurisdictional and Ripeness Issues Are Interrelated.

The Secretary argues that the jurisdictional and ripeness issues are dissimilar. Br. in Opp. 16. However, both issues have a common denominator - whether an adequate administrative review mechanism exists for the claims at issue. The Secretary does not dispute that the Council's constitutional and statutory challenges cannot be raised in the administrative review process. Under *McNary v. Haitian Refugee Center*, 498 U.S. 479, 496-97 (1991), that is a major reason why jurisdiction exists. Under *Reno v. Catholic Social Services, Inc.*, 509 U.S. 43, 63-64 (1993), that is a major reason why the vagueness challenge is ripe. In short, if the Seventh Circuit was correct regarding jurisdiction, it was incorrect regarding ripeness. If this Court affirms the Seventh Circuit regarding jurisdiction, just resolution of this case requires reversal of the Seventh Circuit's ripeness holding. Otherwise, substantial constitutional violations will go uncorrected. The Council's members will continue to be deprived of fair enforcement of the regulations and fair notice of the deficiencies for

which they may be penalized, in violation of their due process rights under the Fifth and Fourteenth Amendments. Am. Compl. § 88.

This Court in *Catholic Social Services,* 509 U.S. at 60, recognized the relationship between jurisdiction and ripeness. Cross-Pet. 7. The Secretary does not challenge this Court's conclusion that jurisdiction and the ripeness doctrine "dovetail neatly." *Catholic Social Services,* 509 U.S. at 60. Moreover, the Secretary's attempt to distinguish *Catholic Social Services* is unsuccessful. Br. in Opp. 16-17. The Secretary admits that in *Catholic Social Services* "withholding review would leave such an alien without any means for obtaining judicial review (making the hardship of withholding review severe)." Br. in Opp. 17. The same rationale applies here because the Council's claims cannot be heard in the administrative review process. Cross-Pet. 7-8. This Court should consider both jurisdiction and ripeness just as it has in the past. Cross-Pet. 8 (citing cases).

III. The Vagueness Challenge Is Ripe Under *Abbott Laboratories.*

The Secretary agrees that resolving the ripeness issue requires "an application of the criteria this Court articulated in [*Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967)]" (Br. in Opp. 11), something the Seventh Circuit failed to do. *See* Pet. App. 10a. In purporting to apply the *Abbott Laboratories* factors, however, the Secretary cites cases that do not even consider ripeness. Br. in Opp. 10 (citing *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 495 (1982); *United States v. Mazurie,* 419 U.S. 544, 550 (1975)). Neither of those cases addressed ripeness, and both involved appeals after rulings on the merits, unlike here. The language the Secretary quotes pertains to analyzing the merits of a vagueness challenge, not ripeness or the pleading requirements to survive a mo-

tion to dismiss. The Council's complaint adequately states a claim and the *Abbott Laboratories* factors are satisfied. Cross-Pet. 8-10; *Gardner v. Toilet Goods Ass'n.*, 387 U.S. 158 (1967) (case arose on a motion to dismiss and Court concluded that pre-enforcement challenge was ripe after employing *Abbott Laboratories* factors).

The Secretary now appears to have abandoned much of the Seventh Circuit's rationale for its ripeness holding. The Seventh Circuit said the Council "cannot ask for an all-at-once review but must wait until the agency has worked through the process of adding detail in administrative adjudication." Pet. App. 11a. However, the assumption that standards will get clearer over time through administrative decisions does not apply here. A provider cannot challenge the choice of the remedy or the scope and severity designations in an administrative hearing. Published decisions of administrative law judges do not discuss scope and severity factors or the appropriateness of a particular remedy. Cross-Pet. 12. Thus, no body of administrative law is evolving that clarifies the meaning or application of the scope and severity factors. *Id.* The Secretary does not dispute this. The Secretary merely contends that "an administrative record will demonstrate how the Secretary or state enforcement officials are tailoring enforcement to the particular facts of the case, and may well document the enforcement agency's reasons or justifications for imposing the chosen sanction or corrective action, significantly aiding judicial review." Br. in Opp. 15. The Secretary misses the point. No body of *administrative decisions* is emerging that clarifies the meaning or application of the scope and severity factors, because such challenges cannot be asserted in the administrative review process. Hence, the Seventh Circuit's justification for its ripeness holding does not exist.

The Secretary claims there is no hardship to withholding judicial review. Br. in Opp. 11. But the Secretary has no answer for the assertion that the only way to preserve appeal rights in the administrative review process is to refuse to correct the deficiency and risk termination of one's provider agreement. Cross-Pet. 11. Termination of one's provider agreement can mean going out of business for nursing homes with a high percentage of revenues represented by Medicare. The Secretary tacitly concedes that there is no way to challenge the vagueness of the grid in the administrative review process. Futile exhaustion is burdensome. Under the *Abbott Laboratories* test, the Council's vagueness claim is ripe. The Seventh Circuit's ruling is contrary to *Abbott Laboratories,* 387 U.S. 136; *Gardner v. Toilet Goods,* 387 U.S. 167; and *Catholic Social Services,* 509 U.S. 43.

The Secretary relies heavily on *Lujan v. National Wildlife Fed'n,* 497 U.S. 871, 891 (1990). Br. in Opp. 11, 12, 14 (quoting *Lujan*). However, the language the Secretary quotes is *dicta,* and *Lujan* is distinguishable. In *Lujan,* the National Wildlife Federation ("Federation") sued the BLM and other federal parties alleging violations of various federal statutes in administering the BLM's "land withdrawal review program." Several members of the Federation filed supporting affidavits. But this Court held that the affidavits were insufficient to confer *standing* on the Federation to challenge the government's actions under the program. 497 U.S. at 882-89. After concluding that the Federation lacked standing, the opinion nevertheless includes at pp. 890-94 a "hypothetical inquiry" and "long and abstract discussion of the scope of relief that might have been awarded had the Federation made a sufficient showing of injury. . . ." 497 U.S. at 913 (Blackmun, J. dissenting). The Secretary relies repeatedly on that "hypothetical inquiry" and discussion regarding ripeness here. Br. in Opp. 11, 12, 14. However,

as discussed below, other language from *Lujan's* ripeness discussion *supports* the Council's ripeness assertions.

Lujan also is distinguishable. Unlike here, *Lujan* arose at the summary judgment stage. The Federation's claims also were much broader than the Council's claims here. The Federation asserted an amorphous challenge to the "entirety" of the "land withdrawal review program." 497 U.S. at 890. That program encompassed "1250 or so individual classification terminations and withdrawal revocations." *Id.* The Council's vagueness challenge is much more focused and precise than that in *Lujan.*

The Secretary argues that "[u]ncertainty as to the remedies that will be used to ensure compliance with the lawful substantive standards, however, is not the sort of undue hardship that warrants pre-enforcement review." Br. in Opp. 13 (citing *cf. Texas v. United States*, 118 S. Ct. 1257, 1259-60 (1998) and *Toilet Goods Ass'n. v. Gardner,* 387 U.S. 158,163-64 (1967)). The cited cases do not support the Secretary's argument. Neither case involved regulations that had already been enforced. Neither case involved "uncertainty as to remedies." Unlike here, they involved uncertainty as to whether the regulations would be enforced at all. *Texas,* 118 S. Ct. at 1260 ("Texas has not pointed to any particular school district in which the application of §§ 39.13(a)(7) or (8) is currently foreseen or even likely."); *Toilet Goods,* 387 U.S. at 163 ("At this juncture we have no idea whether or when such an inspection will be ordered and what reasons the Commissioner will give to justify his order.")

IV. The Council's Vagueness Challenge Need Not Be Pursued in Individual Enforcement Proceedings.

The Secretary contends that the Council cannot provide prove vagueness by providing multiple examples of how

the regulations have been randomly applied against its members, and that only individual claims may be brought. Br. in Opp. 15 (quoting *Lujan*, 497 U.S. at 892-93). However, *Lujan* expressly recognized that regulations with "across the board" applicability can be challenged:

> We merely assert that [the "land withdrawal program"] is not an identifiable "final agency action" for purposes of the APA. *If there is in fact some specific order or regulation, applying some particular measure across the board to all individual classification terminations and withdrawal revocations, and if that order or regulation is final, and has become ripe for review in the manner we discuss subsequently in text, it can of course be challenged under the APA by a person adversely affected - and the entire "land withdrawal review program," insofar as the content of that particular action is concerned, would thereby be affected.* But that is quite different from permitting a generic challenge to all aspects of the "land withdrawal review program," as though that itself constituted a final agency action.

497 U.S. at 890-91, n.2 (emphasis added). The highlighted language describes this case. The Secretary's refusal to define six out of the seven scope and severity factors constitutes "final agency action."

The Secretary fails to offer a legitimate reason why a regulatory challenge like this cannot be brought in a representational setting. As the Seventh Circuit stated, "[i]f some nursing homes may litigate on their own, they may litigate through their trade association; we don't see why the fact that other members of the Council have potential Medicare claims should cut off associational representation

and compel independent litigation." Pet. App. 8a. To establish vagueness, the Council can provide *at trial* multiple examples of how the enforcement regulations have been arbitrarily applied. Such evidence would be irrelevant and would not be allowed in an individual administrative appeal because the vagueness of the regulations cannot be challenged in the administrative review process. This case is thus similar to the "pattern and practice" claim in *McNary*, 498 U.S. at 497 ("To establish the unfairness of the INS practices, respondents in this case adduced a substantial amount of evidence, most of which would have been irrelevant in the processing of a particular individual application.").

In the district court, the Council provided affidavits from some of its members setting forth specific applications of the regulations in support of its motion for preliminary injunction. However, the district court never reached the Council's motion for preliminary injunction, but instead granted the Secretary's motion to dismiss. Cross-Pet. 2; Pet. App. 21a. Accordingly, the question on appeal was whether the Council's amended complaint adequately stated a claim. Under the "notice pleading" standards for federal court, the amended complaint was sufficient; the Council did not need to prove its case in the complaint. By affirming the dismissal of the vagueness challenge, the Seventh Circuit effectively required the Council to meet a "heightened pleading standard." Cross-Pet. 12-13. At a minimum, the Seventh Circuit should have remanded the matter and granted the Council leave to amend. *Catholic Social Services*, 509 U.S. at 66-67.

CONCLUSION

For the foregoing reasons, and those set forth in the cross-petition, the conditional cross-petition should be granted and the dismissal of the Council's challenge to the vagueness of the regulations should be reversed.

Respectfully Submitted,

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